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42 CFR Parts 1003 and 1005

Medicare and State Health Care Programs: Fraud and Abuse; Revisions to the Office of Inspector General's Civil Monetary Penalty Rules; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

42 CFR Parts 1003 and 1005

RIN 0936-AA04

Medicare and State Health Care Programs: Fraud and Abuse; Revisions to the Office of Inspector General's Civil Monetary Penalty Rules

AGENCY: Office of Inspector General (OIG), HHS.

ACTION: Proposed rule.

SUMMARY: This proposed rule would amend the civil monetary penalty (CMP or penalty) rules of the Office of Inspector General (OIG) to incorporate new CMP authorities, clarify existing authorities, and reorganize regulations on civil money penalties, assessments and exclusions to improve readability and clarity.

DATES: To ensure consideration, comments must be delivered to the address provided below by no later than 5 p.m. Eastern Standard Time on July 11, 2014.

ADDRESSES: In commenting, please reference file code OIG-403-P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission. However, you may submit comments using one of three ways (no duplicates, please):

1. *Electronically.* You may submit electronically through the Federal eRulemaking Portal at <http://www.regulations.gov>. (Attachments should be in Microsoft Word, if possible.)

2. *By regular, express, or overnight mail.* You may mail your printed or written submissions to the following address: Patrice S. Drew, Office of Inspector General, Department of Health and Human Services, Attention: OIG-403-P, Cohen Building, 330 Independence Avenue SW., Room 5541C, Washington, DC 20201.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By hand or courier.* You may deliver, by hand or courier, before the close of the comment period, your printed or written comments to: Patrice S. Drew, Office of Inspector General, Department of Health and Human Services, Attention: OIG-403-P, Cohen Building, 330 Independence Avenue SW., Room 5541C, Washington, DC 20201.

Because access to the interior of the Cohen Building is not readily available

to persons without Federal Government identification, commenters are encouraged to schedule their delivery with one of our staff members at (202) 619-1368.

Inspection of Public Comments: All comments received before the end of the comment period will be posted on <http://www.regulations.gov> for public viewing. Hard copies will also be available for public inspection at the Office of Inspector General, Department of Health and Human Services, Cohen Building, 330 Independence Avenue SW., Washington, DC 20201, Monday through Friday from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone (202) 619-1368.

FOR FURTHER INFORMATION CONTACT: Tony Maida, (202) 619-0335, or Jill Wright, (202) 619-0335, Office of Counsel to the Inspector General.

SUPPLEMENTARY INFORMATION: EXECUTIVE SUMMARY:

I. Purpose of the Regulatory Action

A. Need For Regulatory Action

The Affordable Care Act of 2010 (Patient Protection and Affordable Care Act, Pub. L. 111-148, 124 Stat. 119 (2010), as amended by the Health Care and Education Reconciliation Act of 2010, Pub. L. 111-152, 124 Stat. 1029 (2010), hereafter ACA) significantly expanded OIG's authority to protect Federal health care programs from fraud and abuse. OIG proposes to update its regulations to codify the changes made by ACA in the regulations. At the same time, OIG proposes updates pursuant to the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 and other statutory authorities, as well as technical changes to clarify and update the regulations.

B. Legal Authority

The legal authority, laid out later in the preamble, for this regulatory action is found in the Social Security Act (Act), as amended by ACA. The legal authority for the proposed changes is listed by the parts of Title 42 of the Code of Federal Regulations that we propose to modify:

1003: 42 U.S.C. 1320a-7(c), 1320a-7a, 1320b-10, 1395w-27(g), 1395w-112(b)(3)(E), 1395w-141(i)(3), 1395y(b)(3)(B), 1395dd(d)(1), 1395mm, 1395nn(g), 1395ss(d), 1396b(m), 1396r-7(b)(3)(B), 1396r-7(b)(3)(C), 1396t(i)(3), 11131(c), 11137(b)(2), and 262a.

1005: 42 U.S.C. 405(a), 405(b), 1302, 1320a-7, 1320a-7a, and 1320c-5.

II. Summary of Major Provisions

We propose changes to the Civil Monetary Penalties (CMP) regulations at

42 CFR part 1003 to implement authorities under ACA and other statutes. ACA provides for CMPs, assessments, and exclusion for:

- Failure to grant OIG timely access to records;
- ordering or prescribing while excluded;
- making false statements, omissions, or misrepresentations in an enrollment application;
- failure to report and return an overpayment; and
- making or using a false record or statement that is material to a false or fraudulent claim.

These statutory changes are reflected in the proposed regulations.

We also propose a reorganization of 42 CFR part 1003 to make the regulations more accessible to the public and to add clarity to the regulatory scheme. We propose an alternate methodology for calculating penalties and assessments for employing excluded individuals in positions in which the individuals do not directly bill the Federal health care programs for furnishing items or services. We also clarify the liability guidelines under OIG authorities, including the Civil Monetary Penalties Law (CMPL); the Emergency Medical Treatment and Labor Act (EMTALA); section 1140 of the Act for conduct involving electronic mail, Internet, and telemarketing solicitations; and section 1927 of the Act for late or incomplete reporting of drug-pricing information.

III. Costs and Benefits

There are no significant costs associated with the proposed regulatory revisions that would impose any mandates on State, local, or tribal governments or the private sector. OIG anticipates that CMP collections may increase in the future in light of the new CMP authorities and other changes proposed in this rule. However, it is difficult to accurately predict the extent of any increase due to a variety of factors, such as budget and staff resources, the number and quality of CMP referrals or leads, and the length of time needed to investigate and litigate a case. In calendar years 2004-2013, OIG collected between \$10.2 million and \$26.2 million in CMP resolutions for a total of over \$165.2 million.

Discussion

I. Background

For over 22 years, OIG has exercised the authority to impose CMPs, assessments, and exclusions in furtherance of its mission to protect the Federal health care programs and their

beneficiaries from fraud, waste, and abuse. As those programs have changed over the last two decades, OIG has received new fraud-fighting CMP authorities in response, including new authorities under ACA. With the addition of new authorities over time, part 1003 has become cumbersome. While adding new authorities, we are also reorganizing part 1003 to improve its readability and clarity. Lastly, we are also addressing several substantive issues in our existing authorities.

This notice of proposed rulemaking is part of a rulemaking identified in the Unified Agenda by the Title “Medicare and State Health Care Programs: Fraud and Abuse; Revisions to the Office of Inspector General’s Safe Harbors Under the Anti-Kickback Statute, Exclusion Authorities, and Civil Monetary Penalty Rules.” OIG contemplates additional rulemaking in the following areas: Exclusion authorities (42 CFR parts 1000, 1001, 1002, 1006, 1007); inflation adjustment for CMPs (42 CFR part 1003); and safe harbors under the anti-kickback statute, a revised definition of remuneration in part 1003, and a codified gainsharing CMP (42 CFR 1001.952, 42 CFR part 1003). Each of the proposed rules is a stand-alone, independent rule, and the public need not wait for all of the proposed rules to be published to submit comments on any one of the proposed rules. Thus, one can comment meaningfully on this proposed rule without having seen the proposed rules concerning exclusion authorities, inflation adjustment for CMPs, or safe harbors under the anti-kickback statute.

A. Overview of OIG Civil Monetary Penalty Authorities

In 1981, Congress enacted the CMPL, section 1128A of the Act (42 U.S.C. 1320a–7a), as one of several administrative remedies to combat fraud and abuse in Medicare and Medicaid. The CMPL authorized the Secretary to impose penalties and assessments on a person, as defined in 42 CFR part 1003, who defrauded Medicare or Medicaid or engaged in certain other wrongful conduct. The CMPL also authorized the Secretary to exclude persons from Medicare and all State health care programs (including Medicaid). Congress later expanded the CMPL and the scope of exclusion to apply to all Federal health care programs. The Secretary delegated the CMPL’s authorities to OIG. 53 FR 12,993 (April 20, 1988). Since 1981, Congress has created various other CMP authorities covering numerous types of fraud and abuse. These new authorities were also

delegated by the Secretary to OIG and were added to part 1003.

B. The Patient Protection and Affordable Care Act of 2010

ACA is the most recent expansion of the CMP provisions and OIG’s ability to protect Federal health care programs from fraud and abuse. Sections 6402(d)(2)(A)(iii) and 6408(a) of ACA amended the CMPL by adding new conduct that would subject a person to penalties, assessments, and/or exclusion from participation in Federal health care programs. The new covered conduct includes: (1) Failure to grant OIG timely access to records, upon reasonable request; (2) ordering or prescribing while excluded when the excluded person knows or should know that the item or service may be paid for by a Federal health care program; (3) making false statements, omissions, or misrepresentations in an enrollment or similar bid or application to participate in a Federal health care program; (4) failure to report and return an overpayment that is known to the person; and (5) making or using a false record or statement that is material to a false or fraudulent claim. *See Act*, section 1128A(a)(8)–(12). We propose to codify these new authorities and remedies at 42 CFR 1003.200(b)(6)–(10), 1003.210(a)(6)–(9), and 1003.210(b)(3).

Section 6408(b)(2) of ACA amended section 1857(g)(1) of the Act (42 U.S.C. 1395w–27(g)(1)), which relates to Medicare Advantage and Part D contracting organizations. *See Act*, section 1860D–12(b)(3)(E) (42 U.S.C. 1395w–112) (incorporating 1857(g) by reference). Through this amendment to the Act, ACA made several changes to these authorities. First, section 6408(b)(2) of ACA clarifies that penalties, and, where applicable, assessments, may be imposed against a Medicare Advantage or Part D contracting organization when its employees or agents, or any provider or supplier who contracts with it, engages in the conduct described in the CMP authorities in section 1857(g) of the Act. This statutory change broadens the general liability of principals for the actions of their agents under our existing regulations at § 1003.102(d)(5) (proposed § 1003.120(c)) to include contracting providers and suppliers who may not qualify as agents of the contracting organization. ACA also provides for penalties and assessments against a Medicare Advantage or Part D contracting organization that: (1) Enrolls an individual without his or her prior consent; (2) transfers an enrollee from one plan to another without his or her prior consent; (3) transfers an enrollee

solely for the purpose of earning a commission; (4) fails to comply with marketing restrictions described in sections 1851(h) or (j) of the Act (42 U.S.C. 1395w–21(h) or (j)) or applicable implementing regulations or guidance; or (5) employs or contracts with any person who engages in the conduct described in section 1857(g)(1).

We propose to codify these new authorities in the proposed regulations at § 1003.400(c) and their corresponding penalties and assessments at § 1003.410. The Centers for Medicare & Medicaid Services (CMS) may also impose sanctions under its authorities related to Medicare Advantage or Part D contracting organizations. Those authorities are at 42 CFR parts 422 and 423.

C. Reorganization of Part 1003

As Congress created additional CMP authorities, corresponding regulations have been added to the existing regulatory structure. Part 1003 is currently structured with each basis for CMPs and assessments listed in § 1003.102, except CMPs pertaining to managed care organizations are listed in § 1003.103(f). Separate sections discuss the penalty and assessment amounts, exclusion provisions, the factors for determining the appropriate penalty and assessment amounts, and the factors for determining whether OIG should impose exclusion. Over time, this structure has become cumbersome. We propose reorganizing part 1003 to make the regulations more accessible to the public and to add clarity to the regulatory scheme. Except for general and procedural subparts, the reorganized part 1003 groups CMP authorities into subparts by subject matter. This revised structure also clarifies the differences between the various CMP authorities and their respective statutory remedies. For certain CMP authorities, penalties, assessments, and exclusion are authorized. For other CMP authorities, only penalties, or penalties and assessments, are authorized. Each subpart is intended to be self-contained, with all the relevant provisions concerning a particular violation included in the same subpart.

D. Factors Relevant to Determining Amount of Penalty and Assessment and Length of Exclusion

As part of the reorganization, we propose modifying the provisions relating to the factors considered in determining the exclusion period and the amount of penalties and assessments for violations. The present structure separately lists factors for certain CMP

violations in § 1003.106(a) and provides additional detail on these factors for certain CMP violations in § 1003.106(b) and (d). This structure is cumbersome and potentially confusing for the reader.

To add clarity and improve transparency in OIG's decision-making processes, we identified the most common issues among the factors listed and created a single, primary list of factors in the proposed § 1003.140. The primary factors are: (1) The nature and circumstances of the violation, (2) the degree of culpability of the person, (3) the history of prior offenses, (4) other wrongful conduct, and (5) other matters as justice may require. As the fifth factor demonstrates, these are illustrative factors rather than a comprehensive list. Unlike factors in the current version of the regulation, these factors would apply to all CMP violations, except as otherwise provided in the subpart relating to a specific subject matter, which may contain additional detail or explanation regarding a factor's applicability to a specific violation. For example, the aggravating factors currently listed in § 1003.106(b)(1) relate to the nature and circumstances of a violation. Because these factors relate most directly to billing issues, the proposed regulations include them in §§ 1003.220, 1003.320, and 1003.420. We are proposing updating the claims-mitigating factor by increasing the maximum dollar amount considered as mitigation from \$1,000 to \$5,000. We believe this updated amount is an appropriate threshold that is consistent with rationale behind the original amount. A dollar threshold as a mitigating factor for CMP purposes differentiates between conduct that could be considered less serious and more serious. Conduct resulting in more than \$5,000 in federal health care program loss is an indication of more serious conduct. Given the changes in the costs of health care since this regulation was last updated in 2002, we believed the \$1,000 threshold was lower than appropriate. We are also proposing to revise the claims-aggravating factor at 1003.106(b)(1)(iii) by replacing "substantial" with "\$15,000 or more." In assigning a dollar value to the aggravating factor, we considered our practices in evaluating conduct for pursuing CMPs and believe that a loss greater than \$15,000 is an indication of serious misconduct. We also believe replacing "substantial" with a specific dollar threshold increases transparency and provides better guidance to the provider community on OIG's evaluation of this factor.

OIG will, however, continue to review the facts and circumstances of a

violation on a case-by-case basis. For instance, when considering the nature and circumstances of any case, OIG will consider, among other things and to the extent they are relevant, the time period over which the conduct occurred, whether a pattern of misconduct is indicated, the magnitude of the violation, the materiality or significance of a false statement or omission, the number of people involved, the number of victims, and whether patients were or could have been harmed.

The proposed changes also clarify that these factors apply to both exclusion determinations made under part 1003 as well as penalty and assessment amount determinations. We are removing § 1003.7(c) in light of this reorganization. The current regulations state, at § 1003.107(c), that the guidelines regarding exclusion determinations are not binding. This language was used to emphasize that only the reasonableness of a period of exclusion is reviewable on appeal as opposed to OIG's decision to impose an exclusion. While OIG's discretion to exercise its exclusion authority remains unreviewable, the § 1003.107(c) language is no longer necessary under the proposed reorganization. The revisions at § 1003.140 more clearly state that the general guidelines relate to the length of exclusion as opposed to the decision whether to exclude an individual.

At § 1003.106(b)(2), the current regulations discuss a person's degree of culpability and list several aggravating circumstances concerning whether a person had knowledge of the violation. We believe the current language is out-of-date in light of all the CMP authorities that have been added to part 1003 over the years. In addition, we have developed significant experience over the past two decades investigating CMP cases and, particularly, evaluating the different levels of knowledge or intent a person may possess. We propose to consider as an aggravating factor a person's having a level of intent to commit the violation that is greater than the minimum intent required to establish liability. This new aggravating factor would more fully reflect our evaluation of a person's intent and more accurately reflect the different levels of intent required under different CMP authorities.

Various CMP authorities have different intent or scienter requirements. Some authorities have a "knows or should know" standard consistent with the False Claims Act standard that includes actual knowledge, deliberate ignorance, or reckless disregard. Some authorities require only negligence and

some have no intent requirement. Through our extensive enforcement history, we have considerable experience in investigating and evaluating scienter evidence and determining a person's level of intent in committing the violation. In cases when the "knows or should know" standard applies, actual knowledge is considered more egregious than a lower level of intent. When the violation has a strict-liability standard, OIG evaluates the evidence to determine whether the violation was the result of reckless disregard, actual knowledge, or any other level of intent. We intend to continue this practice and intend the general "degree of culpability" factor to encompass this practice.

We also propose to clarify that possessing a lower level intent to commit a violation is not a defense against liability, a mitigating factor, or a justification for a less serious remedy. Individuals and entities are expected to know the law and Federal health care program rules. While the degree of culpability is relevant in our determination to impose a monetary or exclusion remedy, other factors, such as the nature and circumstances of the violation, may justify a maximum monetary remedy or exclusion to protect the Federal health care programs and beneficiaries from fraud, waste, and abuse.

In addition, we propose to add a mitigating circumstance to the degree-of-culpability factor for taking "appropriate and timely corrective action in response to the violation." The proposed regulation requires that a person, to qualify as taking corrective action, disclose the violation to OIG through the Self-Disclosure Protocol (Protocol) and fully cooperate with OIG's review and resolution of the violation. We have long emphasized the importance of compliance programs that result in appropriate action when Federal health care program compliance issues are identified. We continue to believe that appropriate action for potential violations of OIG's CMP authorities must include self-disclosure and cooperation in the inquiry and resolution of the matter. We do not believe that without self-disclosure through the Protocol, the person qualifies for mitigation of the potential monetary or exclusion remedies.

The proposed change clarifies that when we are determining the appropriate remedy against an entity, aggravating circumstances include the prior offenses or other wrongful conduct of: (1) The entity itself; (2) any individual who had a direct or indirect ownership or control interest (as

defined in section 1124(a)(3) of the Act (42 U.S.C. 1320a–3)) in the sanctioned entity at the time the violation occurred and who knew, or should have known, of the violation; or (3) any individual who was an officer or a managing employee (as defined in section 1126(b) of the Act (42 U.S.C. 1320a–5)) of the entity at the time the violation occurred. We also propose to change “any other public or private program for reimbursement for medical services” to “in connection with the delivery of a health care item or service.” This change broadens the types of prior offenses or conduct that we may consider to include private insurance fraud in addition to other offenses that have a nexus to the delivery of health care items or services. Also, this proposed change would be consistent with the aggravating circumstance “other wrongful conduct” at proposed § 1003.140(a)(4).

Finally, the proposed rule would clarify when OIG considers the financial condition of a person in determining penalty or assessment amounts. The current regulations discuss financial condition in various sections with varying degrees of specificity: § 1003.106(a)(1)(iv); (a)(3)(i)(F); (a)(4)(iv); (b)(5); and (d)(4). We propose a more uniform and specific standard to apply after OIG evaluates the facts and circumstances of the conduct and weighs the aggravating and mitigating factors to determine an appropriate penalty and assessment amount. Once OIG proposes this penalty and assessment amount, the person may request that OIG consider its ability to pay the proposed amount. To permit OIG to evaluate a person’s ability to pay, the person must submit sufficient documentation that OIG deems necessary to conduct its review, including audited financial statements, tax returns, and financial disclosure statements. This ability to pay review may also consider the ability of the person to reduce expenses or obtain financing to pay the proposed penalty and assessment. If a person requested a hearing in accordance with 42 CFR 1005.2, the only financial documentation subject to review would be that which the person submitted to OIG, unless the ALJ finds that extraordinary circumstances prevented the person from providing the financial documentation to the OIG in the time and manner requested by the OIG prior to the hearing request.

E. Technical Changes and Clarifications

Because we intend each subpart to be self-contained, we propose incorporating the exclusion sections,

which are currently found at §§ 1003.105 and 1003.107, into the subparts in which exclusion is available: False Claims; Anti-kickback and Physician Self-Referral; EMTALA; and Beneficiary Inducement. This proposed revision more clearly reflects the statutory scheme, which permits both monetary and exclusion remedies for these violations.

The proposed changes clarify in each subject matter subpart that we may impose a penalty for each individual violation of the applicable provision. As we explain below, the statutory authorities are clear that each act that constitutes a violation is subject to penalties. The proposed revisions to the regulatory language better reflect this statutory framework.

Throughout part 1003, we propose replacing references to Medicare and State health care programs with “Federal health care programs” when the provision concerns exclusion to more completely reflect the full scope of exclusion. The proposed changes also remove all references to the penalties and assessments available before 1997 because any conduct prior to 1997 falls outside the CMPL’s statute of limitations.

The proposed changes clarify that a principal’s liability for the acts of its agents does not limit liability only to the principal. Agents are still liable for their misconduct. In our enforcement litigation, we have encountered the argument that agents are not liable for their misconduct where the principal is liable for the same misconduct. We believe the current law provides that the agent remains liable for his or her conduct and may not use the principal as a liability shield. The proposed revision clarifies this point. In addition, we propose to consolidate the current § 1003.102(d)(1)–(4), which addresses situations in which multiple parties may have liability for separate CMP provisions. This proposed revision clarifies that each party may be held liable for any applicable penalties and that the parties may be held jointly and severally liable for the assessment.

II. Provisions of the Proposed Rule

A. Civil Monetary Penalty Authorities

Subpart A—General Provisions

Subpart A contains the general provisions that apply to part 1003. The proposed changes revise the “Basis and Purpose” section to state more succinctly part 1003’s purpose and to include a complete listing of CMPs. We also propose updates to statutory authority citations at proposed § 1003.100(a)–(b).

1003.110 Definitions

The proposed revision includes several changes to the “Definitions” section, proposed § 1003.110 (current § 1003.101), for clarity and readability. First, we propose to redesignate § 1003.101 as § 1003.110. We propose to remove terms from this part that duplicate definitions in part 1000 or are no longer used in this part. We also propose clarifying the definition of “knowingly,” currently found at § 1003.102(e), to cover acts as opposed to information.

Claim

We propose to revise the definition of “claim” by changing the word “to” in the current definition to “under.” This change more closely aligns the regulations to the CMPL’s definition of “claim” to avoid any misinterpretation that a claim is limited to an application for payment for an item or service made directly to a Federal health care program (e.g., a claim also includes applications for payment to contractors).

Contracting Organization

We propose to update the definition of “contracting organization” to include all entities covered by sections 1857, 1860D–12, 1876(b) (42 U.S.C. 1395mm(b)), or 1903(m) of the Act.

Item or Service

We propose revisions to the definition of the term “item or service.” Section 1128A of the Act provides that the term “item or service” “includes” various items, devices, supplies, and services. By using the word “includes” in section 1128A, Congress created an illustrative statutory definition that is broad enough to capture all the uses of the term in section 1128A of the Act. The term is used in section 1128A of the Act in two different contexts: One, in reference to submitting claims for items and services reimbursed by a Federal health care program, and two, in the definition of “remuneration” to beneficiaries in reference to section 1128A(a)(5) of the Act. We propose clarifying the definition to ensure that it reflects the broad meaning of “item or service” in both contexts.

Knowingly

We also propose removing the reference to the False Claims Act from the definition of “knowingly” because it is unnecessary. As used in part 1003, the term “knowingly” applies only to acts, such as the act of presenting a claim. When a person’s awareness or knowledge of information is at issue, the CMPL and other statutes use either a “knows or should know” or a “knew or

should have known” construction. “Knowingly” is defined at section 1128A(i)(7) of the Act. For example, section 1128A(a)(2) of the Act subjects a person to liability when the person knowingly presents, or causes to be presented, a claim that the person knew or should have known is false or fraudulent. Here, the act is presenting the claim or causing the claim to be presented. The information is that the claim was false or fraudulent.

Material

We propose a definition of “material” that mirrors the False Claims Act definition.

Overpayment

We propose a definition of “overpayment” that is taken from section 1128J(d)(4) of the Act (42 U.S.C. 1320a–7k(d)(4)), as amended by section 6402(a) of ACA.

Reasonable Request

We propose a definition of “reasonable request” as part of implementing the new ACA CMP authority for failure to grant OIG timely access to records, as discussed below under § 1003.200, Subpart B.

Responsible Official and Select Agent Program

We propose definitions of “Responsible Official” and “Select Agent Program” as these terms relate to the select agent and toxin CMP authority. We propose to amend the definition of “select agent and toxin” as the term relates to the select agent and toxin CMP authority (42 U.S.C. 262a(i); Act, section 1128A(j)(2)).

Responsible Physician

We also propose revising the definition of “responsible physician” to more closely conform to statutory intent, as discussed below under § 1003.500, Subpart E.

Separately Billable Item or Service and Non-Separately-Billable Item or Service

We also propose definitions of “separately billable item or service” and “non-separately-billable item or service” to create an alternate method for calculating penalties and assessments for violations of section 1128A(a)(6) of the Act, as discussed below.

1003.140 Determinations Regarding the Amount of Penalties and Assessments and the Period of Exclusion

As explained above, the proposed regulation would consolidate the

aggravating and mitigating factors that OIG would consider when determining penalty and assessment amounts and periods of exclusion in proposed § 1003.140. Proposed § 1003.140(c)–(d) clarifies that if any single aggravating circumstance is present: (1) The imposition of a penalty and assessment at or close to the maximum amount may be justified and (2) if exclusion is available, the person should be excluded.

1003.150 Delegation of Authority

The proposed rule also adds an express delegation of authority from the Secretary to OIG to impose penalties, assessments, and exclusions against persons that violate any of the provisions of part 1003. Currently, several **Federal Register** notices and delegation letters, spanning over 20 years, delegate various authorities to OIG. Some of these older notices and letters are no longer easily accessible by the public, such as 53 FR 12,993 (April 20, 1998). This provision, at proposed § 1003.150, reiterates OIG’s existing authority to pursue these matters.

1003.160 Waiver of Exclusion

We also propose changes to part 1003’s exclusion-waiver provisions to clarify the criteria for a waiver request from a State agency. Currently, the regulations state that OIG will consider an exclusion waiver request from a State agency for exclusions imposed pursuant to 42 CFR 1003.102(a), (b)(1), and (b)(4) and 1003.105(a)(1)(ii) under certain circumstances. We propose updating the regulations to permit an administrator of a Federal health care program to request a waiver, similar to the waiver in part 1001. Also, we propose removing the limitations concerning when a waiver may be requested by such administrator.

Subpart B—CMPs, Assessments, and Exclusions for False or Fraudulent Claims and Other Similar Misconduct

Subpart B contains most of the provisions found in the current regulations at § 1003.102(a) and several of the provisions in the current § 1003.102(b). The text of the proposed provisions remains largely unchanged from the current version, except for a separate provision we created to address section 1128A(a)(6) of the Act. Section 1128A(a)(6) of the Act subjects persons to liability for arranging or contracting with (by employment or otherwise) a person that the person knows or should know is excluded from participation in a Federal health care program for the provision of items or services for which payment may be made under that program. This authority is included in

the current regulations describing false or fraudulent claims at § 1003.102(a)(2). Because of our desire to improve the clarity of the regulations generally and because of the proposed penalty and assessment provisions discussed below, the proposed regulation would address section 1128A(a)(6) of the Act in a separate subsection at § 1003.200(b)(4).

On the basis of our lengthy experience enforcing section 1128A(a)(6) of the Act, we are proposing an alternate methodology for calculating penalties and assessments. This alternate methodology recognizes the variety of ways in which items and services are reimbursed by Federal health care programs and the numerous types of health care professionals and other individuals and entities that contribute to the provision of those items and services.

Excluded individuals and entities may be involved in providing items and services in two ways. First, an excluded person may provide items or services that are identifiable on claims submitted by the person or another person (*i.e.*, separately billable items or services). These include items or services for which the excluded person may directly bill under such person’s provider number or where the person assigned their provider number to another entity, such as an employer. In this case, the items or services for which no payment may be made are identifiable because the claims should include the identity of the person that provided the item or service. For example, the performing physician’s provider number should be listed on claims for office visits. If the performing physician is excluded, then the entire claim for the office visit is prohibited.

An excluded person may also provide, furnish, order, or prescribe items or services that are billed by another person, who also is involved in providing the item or service. In this situation, the claim itself may not identify the excluded person by name or provider number. For example, a claim for a prescription drug may not include the identity of the prescribing physician or dispensing pharmacist. The claim for the prescription drug is a separately billable item because it is an item for which an identifiable payment is made. If either the prescribing physician or the dispensing pharmacist is excluded, the claim for the drug is prohibited. The same would be true for a physician who orders a diagnostic test. If the physician who orders the diagnostic test is excluded, the claim for the test is prohibited regardless of who provides and bills for the test.

The second way an excluded individual or entity may be involved in providing items and services is through non-separately billable items or services. Many health care professionals and other individuals and entities are involved in providing items and services that are included within the federal health care program's payment for the item or service. In the physician office visit example, the nurse employed by the physician also contributes to the office visit paid for by the programs. The nurse's services are not separately billable, but are included as part of the claim made for the office visit and are included in the program's reimbursement.

We interpret "the provision of items or services" to include furnishing, providing, ordering, or prescribing an item or service. Thus, an excluded pharmacist furnishes or provides every prescription that he or she fills. Each prescription is separately billable, and under the CMPL, OIG may collect the full amount of each prescription the pharmacist fills while excluded. This analysis extends to each person who is in the supply chain or who has a role in the process that leads to an item or a service provided. For example, a manufacturer, a wholesaler, and a distributor have all participated in providing an item or a service.

Difficulties exist in determining the appropriate penalty and assessment amount for claims that are not separately billable by the excluded person. The Federal health care programs' movement to various forms of bundled and prospective payment has increased these difficulties over time. In light of these changes, the involvement of a single excluded person could cause the total bundled claim or prospective payment to be prohibited. When the excluded person provides items and services that are not separately billable, prohibiting the entire payment could lead to disproportionate assessment amounts in comparison to the harm to the programs. We believe the proposed alternate methodology achieves the purpose of section 1128A(a)(6) of the Act while recognizing the programs' various reimbursement methods and the different types of individuals and entities that may be involved in providing items and services.

The proposed regulations address how penalties and assessments will be imposed for two distinct types of violations: (1) Instances when items or services provided by the excluded person may be separately billed to the Federal health care programs and (2) instances when the items or services provided by the excluded person are not

separately billable to the Federal health care programs, but are reimbursed by the Federal health care program in some manner as part of the item or service claimed.

To achieve this distinction, we propose to define two new terms: "separately billable item or service" and "non-separately-billable item or service." A "separately billable item or service" is defined as "an item or service for which an identifiable payment may be made under a Federal health care program." This type of item or service exists when a person provides, furnishes, orders, or prescribes an identifiable item or service for which a claim for reimbursement may be made to a Federal health care program, e.g., a physician office visit, by either the person or another person.

A "non-separately-billable item or service" is defined as "an item or service that is a component of, or otherwise contributes to the provision of, an item or service, but is not itself a separately billable item or service." Non-separately-billable items or services are reimbursed as part of the claim submitted under the applicable payment methodology, e.g., nursing services associated with a physician office visit, care covered by the skilled nursing facility per diem payment, nursing care covered by a hospital diagnosis-related group (DRG) payment, or radiology technician services associated with a specific procedure.

In instances when the item or service provided by the excluded person is separately billable, the employing or contracting person would continue to be subject to penalties and assessments based on the number and value of those separately billable items and services. For instances when the item or service provided by the excluded person is non-separately-billable, we propose an alternate methodology to calculate penalties and assessments. Penalties would be based on the number of days the excluded person was employed, was contracted with, or otherwise arranged to provide non-separately-billable items or services. Assessments would be based on the total costs to the employer or contractor of employing or contracting with the excluded person during the exclusion, including salary, benefits, and other money or items of value.

We believe the per-day penalty would achieve the purposes of section 1128A(a)(6) of the Act by penalizing the act of employing or otherwise contracting with the excluded person in proportion to the number of days the prohibited relationship with the excluded person existed. In the claims-

based penalty provisions of section 1128A, the number of penalties increases by the number of claims submitted. We propose that similarly the number of penalties increase by the number of days the prohibited relationship with the excluded person existed.

We believe the cost-based assessment achieves the purposes of section 1128A(a)(6) of the Act by capturing the value of the excluded person to the employing or contracting person. The value of an excluded person includes, but is not limited to, salary, health insurance, disability insurance, and employer taxes paid related to the employment of the individual (e.g., employer's share of Federal Insurance Contributions Act (FICA) and Medicare taxes). The health care industry has been on notice for over a decade that employing or contracting with excluded persons who provide items or services paid for by the Federal health care programs is prohibited. See Special Advisory Bulletin on the Effect of Exclusion From Participation in Federal Health Care Programs, 64 FR 52,791 (Sept. 30, 1999). We also recognize, however, that billable items or services generally include numerous non-separately-billable items or services. The involvement of one excluded person can cause the entire claim to be prohibited when a number of other individuals and entities that were not excluded may have been involved in the claim. Through the proposed regulation, we seek to avoid this disproportionate result for purposes of calculating the assessment. We believe that the total costs paid by the employing or contracting person with respect to the excluded person appropriately represents the value of non-separately-billable items or services that the excluded person provided during his, her, or its period of employment or contract.

As discussed above, ACA added five new violations and corresponding penalties to the CMPL. These new violations and the corresponding penalties are at proposed §§ 1003.200(b)(6)-(10), 1003.210(a)(6)-(9), and 1003.210(b)(3). The proposed regulatory text closely mirrors the statutory text. However, section 6402(d)(2)(A) of ACA amends the CMPL by adding a violation for knowingly making or causing to be made "any false statement, omission, or misrepresentation of a material fact in any application, bid, or contract to participate or enroll as a provider of services or a supplier under a Federal health care program." (Emphasis added.) ACA does not, however, include

the word “omission” in its description of the penalty and assessment for this violation. In order to give full effect to the amendment adding “omission” to the CMPL, OIG believes the word “omission” must also be included in the penalty and assessment sections.

Also, we propose clarifying the penalty at section 1128A of the Act, as amended by section 6402(d)(2) of ACA, for failure to report and return overpayments. Under the amended section 1128J(d) of the Act, overpayments must be reported and returned by the later of 60 days after the date the overpayment was identified or the date any corresponding cost report is due, if applicable. The new CMPL authority under section 1128A(a)(10) of the Act does not contain a specific penalty amount, but instead uses the default penalty amount in the CMPL, which is up to \$10,000 for each item or service. In this context, we have proposed regulatory text interpreting the CMPL’s default penalty as up to \$10,000 for each day a person fails to report and return an overpayment by the deadline in section 1128J(d) of the Act. Because the act that creates liability under section 1128A(a)(10), failing to report and return overpayments within 60 days of identification, is based on the 60-day period passing, we believe that the penalty could be interpreted to attach to each following day that the overpayment is retained. However, we note that Congress specified a per day penalty in sections 1128A(a)(4) and (12) and did not do so for section 1128A(a)(10). Thus, we also solicit comments on whether to interpret the default penalty of up to \$10,000 for each item or service as pertaining to each claim for which the provider or supplier identified an overpayment.

Section 6408(a)(2) of ACA amends the CMPL by adding a violation for failure to grant timely access, upon reasonable request, to OIG for the purpose of audits, investigations, evaluations, or other statutory functions. Section 1128(b)(12) of the Act and 42 CFR 1001.1301 currently authorize exclusion based on similar, but not identical, conduct—failure to grant immediate access. We believe Congress expanded OIG’s authority to exclude, and created an authority to impose a penalty, in a broader set of circumstances than covered by section 1128(b)(12) of the Act by using the phrase “timely access” in section 6408(a)(2) of ACA. Thus, we believe conduct that implicates section 1128(b)(12) of the Act is a subset of the conduct implicated by the new CMPL authority created by section 6408(a)(2) of ACA. In these situations, OIG has the discretion to choose whether to pursue

exclusion under section 1128(b)(12) of the Act or penalties and/or exclusion under section 6408(a)(2) of ACA. In drafting regulations pursuant to section 6408(a)(2) of ACA, we evaluated the conduct covered by section 1128(b)(12) to ensure that this proposed rule is consistent with § 1001.1301.

The proposed definitions of “failure to grant timely access” and “reasonable request” give OIG flexibility to determine the time period in which a person must respond to a specific request for access depending on the circumstances. Given the different purposes for which OIG may request access to material, such as audits, evaluations, investigations, and enforcement actions, we believe the best approach to defining these terms is for OIG to specify the date for production or access to the material in the OIG’s written request. In making this decision, OIG will consider the circumstances of the request, including the volume of material, size and capabilities of the party subject to the request, and OIG’s need for the material in a timely way to fulfill its responsibilities. The exception to this approach is a case when OIG has reason to believe that the requested material is about to be altered or destroyed. Under those circumstances, timely access means access at the time the request is made. This exception is the same as provided in § 1001.1301.

Finally, we propose revisions to the current regulation’s aggravating factors for these violations. The aggravating factors listed in proposed § 1003.220 are based on those that apply to the violations in the current regulations. We propose moving the aggravating factors to one section and consolidating similar factors into one factor. For instance, the first aggravating factor, *i.e.*, the violations were of several types or occurred over a lengthy period of time, is found at current § 1003.106(b)(1)(i). We interpret the phrase “several types” to include, but not be limited to, billing for services that are covered by different billing codes. The final aggravating factor relates to the amount or type of financial, ownership, or control interest, or the degree of responsibility a person has in an entity with respect to actions brought under § 1003.200(b)(3). While we will consider whether a person is a CEO or a manager, job titles alone will not guide our consideration of this factor; we will look at the degree of responsibility and influence that a person has in an entity.

Subpart C—CMPs, Assessments, and Exclusions for Anti-Kickback and Physician Self-Referral Violations

Subpart C contains the anti-kickback and physician self-referral provisions, which are found in the current regulations at § 1003.102(a)(5), (b)(9), (b)(10), and (b)(11). The proposed changes include various technical corrections to improve readability and ensure consistency with the statutory language.

We propose revising the provisions relating to the physician self-referral law to incorporate statutory terms that are unique to this statute (section 1877 of the Act (42 U.S.C. 1395nn)). These revisions include using “designated health service” instead of “item or service” and “furnished” instead of “provided.” In addition, we propose revising the authority regarding “cross-referral arrangements” in the current regulations at § 1003.102(b)(10) to more closely reflect the statutory language. Section 1877(g)(4) of the Act provides for CMPs and exclusion against any physician or other person that enters into any arrangement or scheme (such as a cross-referral arrangement) that the physician or other person knows, or should know, has a principal purpose of ensuring referrals by the physician to a particular person that, if the physician directly made referrals to such person, would violate the prohibitions of 42 CFR 411.353. The current regulations, at § 1003.102(b)(10)(i), contain an example of a cross-referral arrangement whereby the physician-owners of entity “X” refer to entity “Y” and the physician-owners of entity “Y” refer to entity “X” in violation of 42 CFR 411.353. While this is one example of a cross-referral arrangement, cross-referral arrangements and circumvention schemes can take a variety of forms. The proposed changes to the regulatory language more closely align the regulations to the statute to avoid any misinterpretation that § 1003.102(b)(10)(i) limits the conduct that circumvents the prohibitions of the physician self-referral law.

The proposed changes also include minor technical corrections to the anti-kickback statute authorities to improve consistency with the statute. First, we added the phrases “to induce” and “in whole and in part” to § 1003.300(d) to better mirror the statutory language. The proposed change also clarifies that the anti-kickback CMP statute, at sections 1128B(b) and 1128A(a)(7) of the Act, permits imposing a penalty for each offer, payment, solicitation, or receipt of remuneration and that each action constitutes a separate violation. In

addition, we include the statutory language stating that the calculation of the total remuneration for purposes of an assessment does not consider whether any portion of the remuneration had a lawful purpose.

Subpart D—CMPs and Assessments for Misconduct by a Managed Care Organization

Subpart D contains the proposed provisions for penalties and assessments against managed care organizations. We propose several stylistic changes to the regulations currently listed at § 1003.103(f). We changed the verbs in this subpart from past tense to present tense to conform to the statutory authorities and many other regulations in this part. The proposed regulation also removes superfluous phrases, such as “in addition to or in lieu of other remedies available under law.” The proposed regulation replaces references to “an individual or entity” with “a person” because “person” is defined in the general section as an individual or entity. The proposed regulation also removes the phrase “for each determination by CMS.” OIG may impose CMPs in addition to or in place of sanctions imposed by CMS under its authorities.

We also added to the regulations OIG’s authority to impose CMPs against Medicare Advantage contracting organizations pursuant to section 1857(g)(1) of the Act and against Part D contracting organizations pursuant to section 1860D–12(b)(3) of the Act.

As discussed above, ACA amended several provisions of the Act that apply to misconduct by Medicare Advantage or Part D contracting organizations. We have included these provisions in the proposed regulations. We added the change in section 6408(b)(2)(C) of ACA regarding assessing penalties against a Medicare Advantage or Part D contracting organization when its employees or agents, or any provider or supplier that contracts with it, violates section 1857. We propose to add the five new violations created in ACA, and their corresponding penalties, at § 1003.400(c). We also propose to include the new assessments, which are available for two of the five new violations, at § 1003.410(c). The proposed regulatory text closely mirrors that of the statute.

The violations in this subpart are grouped according to the contracting organizations they apply to. For instance, § 1003.400(a) violations apply to all contracting organizations. Section 1003.400(b) violations apply to all Medicare contracting organizations, *i.e.*, those with contracts under sections

1857, 1860D–12, or 1876. Section 1003.400(c) violations apply to Medicare Advantage and Part D contracting organizations, *i.e.*, those with contracts under sections 1857 or 1860D–12 of the Act. Section 1003.400(d) violations apply to Medicare Advantage contracting organizations, *i.e.*, those with contracts under section 1857 of the Act. Section 1003.400(e) violations apply to Medicaid contracting organizations, *i.e.*, those with contracts under section 1903(m) of the Act.

We also propose to remove the definition of “violation,” which is currently found at § 1003.103(f)(6), because throughout this part, violation means each incident or act that violates the applicable CMP authority. We also propose including aggravating circumstances to be used as guidelines for taking into account the factors listed in proposed § 1003.140. These aggravating circumstances are adapted from those listed in the current regulations at §§ 1003.106(a)(5) and 1003.106(b)(1) and those published in the **Federal Register** in July 1994. 59 FR 36072 (July 15, 1994).

Subpart E—CMPs and Exclusions for EMTALA Violations

Subpart E contains the penalty and exclusion provisions for violations of EMTALA, section 1867 of the Act (42 U.S.C. 1395dd). EMTALA, also known as the patient antidumping statute, was passed in 1986 as part of the Consolidated Omnibus Budget Reconciliation Act of 1985 (COBRA), Public Law 99–272. Section 1867 of the Act sets forth the obligations of a Medicare-participating hospital to provide medical screening examinations to individuals who come to the hospital’s emergency department and request examination or treatment for a medical condition. EMTALA further provides that if the individual has an emergency medical condition, the hospital is obligated to stabilize that condition or to arrange for an appropriate transfer to another medical facility where stabilizing treatment can be provided. EMTALA also requires hospitals with specialized capabilities or facilities to accept appropriate transfers of individuals from other hospitals. Finally, EMTALA creates obligations for physicians responsible for the examination, treatment, or transfer of an individual in a participating hospital, including a physician on-call for the care of that individual. The regulations created pursuant to section 1867 of the Act are found at 42 CFR 489.24.

Under section 1867(d) of the Act, participating hospitals and responsible physicians may be liable for CMPs of up to \$50,000 (\$25,000 for hospitals with fewer than 100 State-licensed and Medicare-certified beds) for each negligent violation of their respective EMTALA obligations. Responsible physicians are also subject to exclusion for committing a gross and flagrant or repeated violation of their EMTALA obligations. OIG’s regulations concerning the EMTALA CMPs and exclusion are currently at 42 CFR 1003.102(c), 103(e) and 106(a)(4) and (d).

We propose several clarifications to the EMTALA CMP regulations. First, as part of our proposed general reorganization, we have included the EMTALA authorities within a separate subpart. Further, the proposed revision removes outdated references to the pre-1991 “knowing” scienter requirement. We also propose minor revisions to clarify that the CMP may be assessed for each violation of EMTALA and that all participating hospitals subject to EMTALA, including those with emergency departments and those with specialized capabilities or facilities, are subject to penalties.

As discussed above, we propose revising the “responsible physician” definition to clarify that on-call physicians at any participating hospital subject to EMTALA, including the hospital the individual initially presented to and the hospital with specialized capabilities or facilities that has received a request to accept an appropriate transfer, face potential CMP and exclusion liability under EMTALA.

Section 1867(d) of the Act provides that any physician who is responsible for the examination, treatment, or transfer of an individual in a participating hospital, including any physician on-call for the care of such an individual, and who negligently violates section 1867 may be penalized under section 1867(d)(1)(B). The current definition of “responsible physician” also provides for on-call physician liability. We propose to revise the definition to clarify the circumstances when an on-call physician has EMTALA liability. An on-call physician that fails or refuses to appear within a reasonable time after such physician is requested to come to the hospital for examination, treatment, or transfer purposes is subject to EMTALA liability. This includes on-call physicians at the hospital where the individual presents initially and requests medical examination or treatment as well as on-call physicians at a hospital with specialized capabilities or facilities where the

individual may need to be transferred. In addition, an on-call physician at the hospital with specialized capabilities or facilities may violate EMTALA by refusing to accept an appropriate transfer.

Under a plain reading of section 1867(d)(1)(B), the statute makes no distinction between physicians who are on-call at the presenting hospital and those who are on-call at a hospital with specialized capabilities or facilities. In fact, the statute refers to “participating hospitals” and that term includes both. Thus, we propose modifying the definition of “responsible physician” to more clearly reflect the statutory scheme.

We also propose revising the factors, currently set forth in §§ 1003.106(a)(4) and (d), to improve clarity and better reflect OIG’s enforcement policy. First, we propose clarifying that the factors listed in proposed § 1003.520 will be used in making both CMP and exclusion determinations. Further, we propose incorporating the general factors listed in § 1003.140 and provide additional guidance on the EMTALA subpart at proposed § 1003.520. Many of the factors in the current § 1003.106(a)(4) and (d) duplicate those general factors.

Finally, we examined the factors currently at § 1003.106(d) in light of our lengthy enforcement experience. We concluded that for several reasons, the mitigating factors should be removed. Because of the overall statutory purpose, the fact-specific nature of EMTALA violations, and the CMS certification process, the mitigating factors currently found at § 1003.106(d) are not useful in determining an appropriate penalty amount. First, Congress enacted EMTALA to ensure that individuals with emergency medical conditions are not denied essential lifesaving services. 131 Cong. Rec. S13904 (daily ed. Oct. 23, 1985) (statement of Sen. David Durenberger); H.R. Rep. No 99–241, pt. 1, at 27 (1986), reprinted 1986 U.S.C.C.A.N. 579, 605. In light of this statutory purpose, the circumstances surrounding the individual’s presentment to a hospital are important to determinations about whether and to what extent a CMP or an exclusion is appropriate. Thus, the proposed regulations would revise the factors to clarify that aggravating circumstances include: A request for proof of insurance or payment prior to screening or treating; patient harm, unnecessary risk of patient harm, premature discharge, or a need for additional services or subsequent hospital admission that resulted, or could have resulted, from the incident; and whether the individual presented with a medical

condition that was an emergency medical condition. While we removed the language at current § 1003.106(a)(4), we consider these circumstances to be included in the general factors listed at proposed § 1003.140. Thus, while the proposed regulations do not state that OIG will consider “other instances where the respondent failed to provide appropriate medical screening examination, stabilization and treatment of individuals coming to a hospital’s emergency department or to effect an appropriate transfer,” OIG will consider each of these failures when determining a penalty because they relate to a respondent’s prior history.

EMTALA violations necessarily involve a case-by-case inquiry into the circumstances of the incident. Through our enforcement experience, we have found that the current regulation’s mitigating factors do not assist in that inquiry. For example, § 1003.106(d)(5) states that it should be considered a mitigating circumstance if an individual presented a request for treatment, but subsequently exhibited conduct that demonstrated a clear intent to leave the respondent hospital voluntarily. In our enforcement activities, however, we have found situations when the individual may have demonstrated a clear intent to leave because the hospital failed to properly screen the individual within a reasonable amount of time. We do not believe that in this circumstance, the hospital’s penalty should be mitigated. Further, the factor at § 1003.106(d)(6)(A) in the current regulation is not relevant to mitigation because developing and implementing a corrective action plan is a requirement of the CMS certification process following an investigation of an EMTALA violation.

We will continue to evaluate the circumstances of each EMTALA referral to determine whether to exercise our discretion to pursue the violation and to determine the appropriate remedy.

Subpart F—CMPs for Section 1140 Violations

Subpart F applies to violations of section 1140 of the Act (42 U.S.C. 1320b–10). The most significant proposed change to this subpart is clarifying the application of section 1140 of the Act to telemarketing, Internet, and electronic mail solicitations. Section 1140 of the Act prohibits the use of words, letters, symbols, or emblems of the Department of Health and Human Services (HHS), CMS, Medicare, or Medicaid in connection with “an *advertisement, solicitation, circular, book, pamphlet, or other communication*, or a play, motion

picture, broadcast, telecast, or *other production*” in a manner that could reasonably be interpreted as conveying the false impression that HHS, CMS, Medicare, or Medicaid has approved, endorsed, or authorized such use. (Emphasis added.)

We previously defined conduct that constituted a violation for (1) direct or printed mailing solicitations or advertisements and (2) broadcasts or telecasts. The proposed regulations are updated also to reflect telephonic and Internet communications. Under a plain reading of the Act, telemarketing solicitations, email, and Web sites fall within the statutory terms emphasized above. We believe these communications are analogous to, and therefore propose imposing penalties that would apply in the same manner as, those for direct mail and other printed materials. The number of individuals who received direct mail and other printed materials can be more easily quantified than the number of individuals who saw a television commercial or heard a radio commercial. Telemarketing calls, electronic messages, and Web page views can be similarly quantified. Thus, we propose subjecting telemarketing, email, and Web site violations to the same \$5,000 penalty as printed media. Each separate email address that received the email, each telemarketing call, and each Web page view would constitute a separate violation. We are also soliciting comments on how to interpret section 1140 in the context of social media, such as Facebook and Twitter.

Subpart G—Reserved

Subpart H—CMPs for Adverse Action Reporting and Disclosure Violations

Subpart H covers violations for failing to report payments in settlement of a medical malpractice claim in accordance with section 421 of Public Law 99–660 (42 U.S.C. 11131); failing to report adverse actions pursuant to section 221 of Public Law 104–191 as set forth in section 1128E of the Act (42 U.S.C. 1320a–7e); or improperly disclosing, using, or permitting access to information reported in accordance with part B of Title IV of Public Law 99–660 (42 U.S.C. 11137).

The language in proposed subpart H remains largely unchanged from the current regulations at § 1003.102(b)(5)–(6) and § 1003.103(c), (g). We propose to remove the reference to the Healthcare Integrity and Protection Data Bank (HIPDB) in conformity with section 6403(a) of ACA, which removed the reference from section 1128E of the Act.

The relevant reporting requirements, violation, and penalties would remain unchanged. Under section 1128E of the Act, providers must still report the same information. Once the HIPDB is phased out pursuant to section 6403(a) of ACA, the information will be collected and stored in the National Practitioner Data Bank established pursuant to the Health Care Quality Improvement Act of 1986 (42 U.S.C. 11101 et seq.). In the penalty section, we propose to clarify that a CMP may be imposed for each failure to report required information or adverse action and for each improper disclosure, use, or permitting of access to information.

Subpart I—CMPs for Select Agent Program Violations

Subpart I contains the penalties for violations involving select agents, currently found at § 1003.102(b)(16) and § 1003.103(l). The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act of 2002), Public 107–188, provides for the regulation of certain biological agents and toxins (referred to below as “select agents and toxins”) by HHS. The regulations created pursuant to the Bioterrorism Act of 2002 are found at 42 CFR part 73. The regulations set forth requirements for the possession and use in the United States, receipt from outside the United States, and transfer within the United States of the select agents and toxins. For each violation of 42 CFR part 73, OIG is authorized to impose CMPs of up to of \$250,000, in the case of an individual, and \$500,000, in the case of an entity.

Proposed subpart I clarifies that the CMP may be assessed for each individual violation of 42 CFR Part 73. The Bioterrorism Act of 2002 states that any person who violates “any provision” of the regulations is subject to the maximum statutory penalty. The plain meaning of “any provision” means that any single violation can subject a person to the maximum penalty. The provisions of 42 CFR 72.7 state that the penalties for a violation of part 73 should be calculated “per event,” also indicating that the maximum penalty may be assessed on a per-violation basis. Thus, we propose amending the regulation to add “each individual” before “violation” to clarify our longstanding interpretation of this section to mean that each violation subjects a person to a CMP up to the maximum amount.

In addition, proposed subpart I includes several aggravating circumstances to guide our penalty determinations. Aggravating factors include: (1) The Responsible Official

participated in or knew or should have known of the violation; (2) the violation was a contributing factor, regardless of proportionality, to an unauthorized individual’s access to or possession of a select agent or toxin, an individual’s exposure to a select agent or toxin, or the unauthorized removal of a select agent or toxin from the person’s physical location as identified on the person’s certificate of registration; and (3) the person previously received a statement of deficiency from HHS or the Department of Agriculture for the same or substantially similar conduct.

Subpart J—CMPs, Assessments, and Exclusions for Beneficiary Inducement Violations

Subpart J covers two statutory provisions concerning beneficiary inducement violations. We propose moving the existing regulation, § 1003.102(b)(13), concerning the beneficiary inducement provision in the CMPL (section 1128A(a)(5) of the Act), to this subpart. We also propose regulatory language for the authority at section 1862(b)(3)(C) of the Act. The statutory authority is self-implementing and does not require a regulation. We propose adding the regulatory language at this time in light of the general reorganization. Under section 1862(b)(3)(C) of the Act, a penalty of up to \$5,000 may be imposed against any person who offers any financial or other incentive for an individual entitled to benefits under Medicare not to enroll, or to terminate enrollment, under a group health plan or a large group health plan that would, in the case of such enrollment, be a primary plan as defined in section 1862(b)(2)(A). The proposed regulatory text closely follows the language of the statute.

We propose to incorporate the general factors listed in § 1003.140 for determining amounts of penalties and assessments for violations in this subpart and to clarify that we will consider the amount of remuneration, other financial incentives, or other incentive. This provision is in the current regulations at § 1003.106(a)(1)(vii).

Subpart K—CMPs for the Sale of Medicare Supplemental Policies

Subpart K covers violations relating to the sale of Medicare supplemental policies. The statutory authority is self-implementing and does not require a regulation. Omnibus Budget Reconciliation Act of 1990, Public Law 101–508, section 4354(c), 104 Stat. 3327 (1990); 42 U.S.C. 1395ss(d). However, we propose adding the regulatory

language at this time in light of the general reorganization.

OIG may impose a penalty against any person who it determines has violated section 1882(d)(1) of the Act (42 U.S.C. 1395ss(d)(1)) by knowingly and willfully making or causing to be made or inducing or seeking to induce the making of any false statement or representation of material fact with respect to the compliance of any policy with Medicare supplemental policy standards and requirements or with respect to the use of the Secretary’s emblem (described at section 1882(a)(1) of the Act (42 U.S.C. 1395ss(a)(1)) indicating that a policy has received the Secretary’s certification. We propose to add this violation at § 1003.1100(a).

OIG may impose a penalty against any person who it determines has violated section 1882(d)(2) of the Act (42 U.S.C. 1395ss(d)(2)) by falsely assuming or pretending to be acting, or misrepresenting in any way that he is acting, under the authority of or in association with, Medicare or any Federal agency, for the purpose of selling or attempting to sell insurance, or in such pretended character demands or obtains money, paper, documents or anything of value. We propose to add this violation at § 1003.1100(b).

OIG may also impose a penalty against any person who it determines has violated section 1882(d)(4)(A) of the Act (42 U.S.C. 1395ss(d)(4)(A)) by mailing or causing to be mailed any matter for advertising, soliciting, offering for sale, or the delivery of Medicare supplemental insurance policy that has not been approved by the State commissioner or superintendent of insurance. We propose to add this violation at § 1003.1100(c).

OIG may impose a penalty against any person who it determines has violated section 1882(d)(3)(A)(i) of the Act (42 U.S.C. 1395ss(d)(3)(A)(i)) by issuing or selling to an individual entitled to benefits under Part A or enrolled in Part B (including an individual electing a Medicare Part C plan) (1) a health insurance policy with the knowledge that the policy duplicates Medicare or Medicaid health benefits to which the individual is otherwise entitled; (2) a Medicare supplemental policy to an individual who has not elected a Medicare Part C plan where the person knows that the individual is entitled to benefits under another Medicare supplemental policy; (3) a Medicare supplemental policy to an individual who has elected a Medicare Part C plan where the person knows that the policy duplicates health benefits to which the individual is otherwise entitled under

the Medicare Part C plan or under another Medicare supplemental policy; and (4) a health insurance policy (other than a Medicare supplemental policy) with the knowledge that the policy duplicates health benefits to which the individual is otherwise entitled, other than benefits to which the individual is entitled under a requirement of State or Federal law. We proposed to add this violation at § 1003.1100(d).

OIG may also impose a penalty against any person who violated section 1882(d)(3)(A)(vi)(II) of the Act (42 U.S.C. 1395ss(d)(3)(A)(vi)(II)) by issuing or selling a health insurance policy (other than a policy described in section 1882(d)(3)(A)(vi)(III) of the Act) to an individual entitled to benefits under Part A or enrolled under Part B who is applying for a health insurance policy without furnishing a disclosure statement (described at section 1882(d)(3)(A)(vii) of the Act). We propose to add this violation at § 1003.1100(e).

OIG may also impose a penalty against any person who it determines has violated section 1882(d)(3)(B)(iv) of the Act (42 U.S.C. 1395ss(d)(3)(B)(iv)) by issuing or selling a Medicare supplemental policy to any individual eligible for benefits under Part A or enrolled under Part B without obtaining the written statement from the individual or written acknowledgement from the seller required by section 1882(d)(3)(B) of the Act (42 U.S.C. 1395ss(d)(3)(B)). We propose to add this violation at § 1003.1100(f).

For violations of section 1882(d)(1), (d)(2), and (d)(4)(A) of the Act, OIG may impose a penalty of not more than \$5,000 for each violation. We propose to add this penalty at § 1003.1110(a). For violations of section 1882(d)(3)(A) and (B) of the Act, OIG may impose a penalty of not more than \$25,000 for each violation by a seller that is also the issuer of the policy and a penalty of not more than \$15,000 for each violation by a seller that is not the issuer of the policy. We propose to add these penalties at § 1003.1110(b) and (c). In determining the amount of the penalty in accordance with proposed subpart K, OIG would consider the factors listed in the proposed § 1003.140.

Subpart L—CMPs for Drug Price Reporting

Subpart L contains the CMPs for drug-price reporting found in section 1927(b)(3)(B)–(C) of the Act (42 U.S.C. 1396r–8(b)(3)(B)–(C)). Although the statutory authority is self-implementing and does not require a regulation, we propose adding the regulatory language at this time in light of the general

reorganization. The proposed regulation text closely mirrors the language of the statute.

Section 1927(a) of the Act and section 340B of the Public Health Service Act implement a drug-pricing program in which manufacturers that sell covered outpatient drugs to covered entities must agree to charge a price that will not exceed an amount determined under a statutory formula. Under section 1927(a) of the Act, manufacturers must provide certain statutorily mandated discounts to covered entities. Section 1927(b)(3)(A) requires manufacturers with Medicaid Drug Rebate Agreements to provide specified drug-pricing and product information to the Secretary, including, but not limited to, average manufacturer price (AMP), average sales price (ASP), wholesale acquisition cost, and best price. Labelers are required to certify each product and pricing data submission made to CMS.

The fact that many manufacturers submit late or incomplete product and pricing data adversely affects the efficient administration of Federal health care programs. *See Drug Manufacturers' Noncompliance With Average Manufacturer Price Reporting Requirements* (OEI–03–09–00060) (September 2010); *Average Sales Prices: Manufacturer Reporting and CMS Oversight* (OEI–03–08–00480) (February 2010); *Deficiencies in the Oversight of the 340B Drug Pricing Program* (OEI–05–02–00072) (October 2005). As described in our Special Advisory Bulletin dated September 28, 2010, OIG inspections have established that manufacturers continue to provide untimely or incomplete pricing data. The September 2010 report found that more than three-quarters of manufacturers failed to comply with quarterly AMP reporting requirements in at least one quarter in calendar year 2008.

In response to the September 2010 report's findings, CMS stated that it would begin referring manufacturers that submit incomplete quarterly and monthly data to OIG for CMP consideration. CMS stated that it would also refer manufacturers that report late or incomplete ASP data. As discussed in two 2010 **Federal Register** notices CMS proposed to establish a process for addressing manufacturers' failure to report manufacturer ASP data in a timely fashion, noting that while delays in reporting ASP data have been uncommon, they create risks. 75 FR 40139, 40153 (July 13, 2010); 75 FR 73169, 73462 (November 29, 2010). CMS further stated that it had recently encountered situations when delays in manufacturer ASP reporting could have

led to significant ASP payment limit fluctuations for highly utilized Health Care Common Procedure Coding System codes (HCPCS). 75 FR at 40153; 75 FR at 73462. To minimize ASP payment limit fluctuations because of missing data, CMS proposed that, in situations when missing ASP data would result in a 10 percent or greater change in the calculation of the HCPCS payment limit for multiple source drugs, CMS would carry over previously reported manufacturer ASP data, as subject to certain conditions. CMS noted that its carryover proposal should not be interpreted by manufacturers to mean that CMS and OIG will refrain from collecting penalties for ASP reporting violations. As stated in the CMS proposal, submission of late reports and failure to submit reports will not be tolerated.

As set forth in the Special Advisory Bulletin dated September 28, 2010, OIG intends to impose CMPs on those manufacturers that submit or certify late or incomplete product and pricing information. Under section 1927(b)(3)(C) of the Act, OIG may impose a penalty of not more than \$10,000 per day for each day that a manufacturer with an agreement under section 1927 of the Act fails to provide the information required by section 1927(b)(3)(A) of the Act.

Manufacturers submit the product and pricing information required by section 1927 using the National Drug Code (NDC) product identifier. Manufacturers submit ASP data to CMS at the 11-digit NDC level, including the number of units of the 11-digit NDC sold. Manufacturers submit AMP data to CMS through the Web-based Drug Data Reporting system at the 9-digit NDC level.

OIG proposes calculating CMPs under section 1927(b)(3)(C) of the Act at the 9-digit NDC level for both AMP and ASP data. For example, a manufacturer that fails to provide the information required by section 1927(b)(3)(A) of the Act for five separate 9-digit level NDCs may be penalized for each item, in an aggregate amount of not more than \$50,000 per day for each day that the information is not provided. If, after 2 days, the manufacturer in this example submitted information for two of the missing drugs, the manufacturer would be subject to an aggregate penalty of not more than \$30,000 per day for each additional day that information was not provided for the remaining three items. OIG believes that this interpretation is supported by the statutory text, which refers to NDCs, and by the reporting systems employed by CMS, under which manufacturers are required to

report AMP and ASP product and pricing data using NDCs.

Section 1927(b)(3)(B) provides for verification surveys of AMPs and establishes that a penalty of not more than \$100,000 may be imposed against a wholesaler, direct seller, or manufacturers that directly distribute their covered outpatient drugs for refusing a request for information by, or for knowingly providing false information to, the Secretary about charges or prices in connection with such a survey.

Pursuant to section 1927(b)(3)(C) of the Act, OIG may impose a penalty of not more than \$100,000 against any manufacturer with an agreement under section 1927 of the Act that knowingly provides false information for each item of false information.

OIG will consider the general factors listed in § 1003.140 when determining the amount of the penalties.

Subpart M—CMPs for Notifying a Skilled Nursing Facility, Nursing Facility, Home Health Agency, or Community Care Setting of a Survey

In subpart M, we propose to add regulations providing for CMPs for notifying a skilled nursing facility, nursing facility, home health agency, or a community care setting of the date or time of a survey. The statutory authority for these CMPs is self-implementing and does not require a regulation. Act, sections 1819(g)(2)(A), 1919(g)(2)(A), 1891(c)(1), 1929(i)(3)(A); 42 U.S.C. 1395i-3(g)(2)(A), 1396r(g)(2)(A), 1395bbb(c)(1), 1396t(i)(3)(A). However, we propose adding the regulatory language at this time in light of the general reorganization. The proposed regulation text closely mirrors the language of the statute.

Skilled nursing facilities (SNF), nursing facilities (NF), home health agencies, and community care settings are subject to State compliance surveys without any prior notice. Sections 1819(g)(2)(A), 1919(g)(2)(A), 1891(c)(1), and 1929(i)(3)(A) of the Act provide for imposing a penalty of not more than \$2,000 against any individual who notifies, or causes to be notified, a SNF, NF, home health agency, or community care setting of the time or date on which a survey is scheduled to be conducted.

OIG will consider the general factors listed in § 1003.140 when determining the amount of the penalties to be imposed under proposed subpart M.

Subpart O—Procedures for the Imposition of CMPs, Assessments, and Exclusions

Subpart O contains the procedural provisions that apply to part 1003. We

propose several clarifying changes to procedures in this subpart. We propose amending the methods permitted for service of a notice of intent to impose a penalty, assessment, or exclusion under part 1003. The current § 1003.109 requires service by certified mail, return receipt requested. Section 1128A(c)(1) of the Act, however, permits service by any method authorized by Rule 4 of the Federal Rules of Civil Procedure (FRCP). This rule has been amended to authorize various service methods depending on whether the recipient is a domestic or foreign individual or corporation. Therefore, we are amending our regulation at § 1003.1500(a) and 1003.1510 to permit service under FRCP Rule 4. By referencing the rule, the regulation would reflect any future amendments to Rule 4 automatically.

We also propose technical changes to the judicial review provision currently at § 1003.127 and redesignated as § 1003.1540 to better conform to the statutory scheme that a person must exhaust his or her administrative remedies before filing a claim in Federal court. Exhaustion of administrative remedies is a well-settled legal principle, particularly concerning section 405(g) of the Act (42 U.S.C. 205(g)). Consistent with existing law, the proposed regulations clarify that a person may not bring a claim in Federal court without first raising that claim at every applicable stage within the administrative process, including any administrative appeal process. In the context of part 1003, that administrative process consists of timely requesting a hearing before an Administrative Law Judge (ALJ) pursuant to 42 CFR 1005.2 and, if the respondent loses at the ALJ level, timely filing an appeal of the ALJ decision to the Departmental Appeals Board. Only after the Departmental Appeals Board makes a final decision under 42 CFR 1005.21(j) is the respondent eligible to file an action in Federal court.

We also propose a technical change to the regulatory language to clarify the statutory limit on issues eligible for judicial review. Section 1128A(e) of the Act provides that “[n]o objection that has not been urged before the Secretary shall be considered by the court, unless the failure or neglect to urge such objection shall be excused because of extraordinary circumstances.” We interpret this to mean that a person is precluded from making arguments or raising issues in Federal court that were not first raised in the administrative process, unless the court finds that extraordinary circumstances prevented raising those arguments or issues. For

example, we interpret “extraordinary circumstances” to mean that those arguments or issues were beyond the authority of the administrative process.

Other Changes in Part 1003

OIG has the authority to impose CMPs against endorsed sponsors under the Medicare Prescription Drug Discount Card Program that knowingly commit certain violations. The discount card program has been defunct since January 1, 2006, when Medicare Part D went into effect. We propose to remove this CMP from the regulations as the statute of limitations has expired for any conduct that might implicate this CMP.

B. Appeals of Exclusions, Civil Monetary Penalties, and Assessments

We propose changes to the OIG regulations at 42 CFR part 1005 to correct an internal inconsistency in § 1005.4(c). The regulation currently states at § 1005.4(c)(5)–(6) that an ALJ is not authorized to (1) review the exercise of discretion by OIG to exclude an individual or entity under section 1128(b) of the Act, (2) determine the scope or effect of the exclusion, or (3) set a period of exclusion at zero when the ALJ finds that the individual or entity committed an act described in section 1128(b) of the Act. Currently, § 1005.4(c)(7) states that an ALJ is not authorized to review the exercise of discretion by OIG to impose a CMP, an assessment, or an exclusion under part 1003. The second and third limits on ALJ authority with respect to exclusions under section 1128(b) of the Act should also apply to exclusions imposed under part 1003. To correct this inconsistency, we propose to clarify that when reviewing exclusions imposed pursuant to part 1003, an ALJ is not authorized to (1) review OIG’s exercise of discretion to exclude an individual or entity, (2) determine the scope or effect of the exclusion, or (3) set a period of exclusion at zero if the ALJ finds that the individual or entity committed an act described in part 1003. We believe that this requirement is consistent with congressional intent in enacting the statutes providing authority for part 1003 that explicitly provide for exclusion as an appropriate remedy for the commission of any of the acts specified in those statutes. Thus, in every case when OIG has exercised its discretion to impose an exclusion and when the ALJ concurs that a violation did occur, exclusion is appropriate.

III. Regulatory Impact Statement

We have examined the impact of this proposed rule as required by Executive Order 12866, Executive Order 13563,

the Regulatory Flexibility Act (RFA) of 1980, the Unfunded Mandates Reform Act of 1995, and Executive Order 13132.

Executive Order Nos. 12866 and 13563

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulations are necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects; distributive impacts; and equity). Executive Order 13563 is supplemental to and reaffirms the principles, structures, and definitions governing regulatory review as established in Executive Order 12866. A regulatory impact analysis must be prepared for major rules with economically significant effects, *i.e.*, \$100 million or more in any given year. This is not a major rule as defined at 5 U.S.C. 804(2); it is not economically significant because it does not reach that economic threshold.

This proposed rule is designed to implement new statutory provisions, including new CMP authorities. This proposed rule is also designed to clarify the intent of existing statutory requirements and to reorganize CMP regulation sections for ease of use. The vast majority of providers and Federal health care programs would be minimally impacted, if at all, by these proposed revisions.

Accordingly, we believe that the likely aggregate economic effect of these regulations would be significantly less than \$100 million.

Regulatory Flexibility Act

The RFA and the Small Business Regulatory Enforcement and Fairness Act of 1996, which amended the RFA, require agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and government agencies. Most providers are considered small entities by having revenues of \$5 million to \$25 million or less in any one year. For purposes of the RFA, most physicians and suppliers are considered small entities.

The aggregate effect of the changes to the CMP provisions would be minimal.

In summary, we have concluded that this proposed rule should not have a significant impact on the operations of a substantial number of small providers and that a regulatory flexibility analysis is not required for this rulemaking.

In addition, section 1102(b) of the Act (42 U.S.C. 1302) requires us to prepare a regulatory impact analysis if a rule

under Titles XVIII or XIX or section B of Title XI of the Act may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to section 604 of the RFA. Only one proposed change has been made under the relevant title, the amendments to the Medicare Contracting Organization Rule at proposed § 1003.400, et seq. This rule applies only to Medicare contracting organizations, not to rural hospitals, and would have no effect on rural hospitals. Thus, an analysis under section 1102(b) is not required for this rulemaking.

Unfunded Mandates Reform Act

Section 202 of the Unfunded Mandates Reform Act of 1995, Public Law 104-4, also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in expenditures in any one year by State, local, or tribal governments, in the aggregate, or by the private sector, of \$110 million. As indicated above, these proposed revisions comport with statutory amendments and clarify existing law. We believe that as a result, there would be no significant costs associated with these proposed revisions that would impose any mandates on State, local, or tribal governments or the private sector that would result in an expenditure of \$110 million or more (adjusted for inflation) in any given year and that a full analysis under the Unfunded Mandates Reform Act is not necessary.

Executive Order 13132

Executive Order 13132, Federalism, establishes certain requirements that an agency must meet when it promulgates a rule that imposes substantial direct requirements or costs on State and local governments, preempts State law, or otherwise has Federalism implications. In reviewing this rule under the threshold criteria of Executive Order 13132, we have determined that this proposed rule would not significantly affect the rights, roles, and responsibilities of State or local governments.

IV. Paperwork Reduction Act

These proposed changes to Parts 1003 and 1005 impose no new reporting requirements or collections of information. Therefore, a Paperwork Reduction Act review is not required.

List of Subjects

42 CFR Part 1003

Fraud, Grant programs—health, Health facilities, Health professions, Medicaid, Reporting and recordkeeping.

42 CFR Part 1005

Administrative practice and procedure, Fraud, Investigations, Penalties.

For the reasons set forth in the preamble, the Office of the Inspector General, Department of Health and Human Services, proposes to amend 42 CFR chapter V, subchapter B as follows:

PART 1003—CIVIL MONEY PENALTIES, ASSESSMENTS AND EXCLUSIONS

■ 1. The authority citation for part 1003 continues to read as follows:

Authority: 42 U.S.C. 262a, 1302, 1320–7, 1320a–7a, 1320b–10, 1395u(j), 1395u(k), 1395cc(j), 1395w–141(i)(3), 1395dd(d)(1), 1395mm, 1395nn(g), 1395ss(d), 1396b(m), 11131(c), and 11137(b)(2).

■ 2. Designate §§ 1003.100 through 1003.135 as Subpart A, and add a heading for subpart A to read as follows:

Subpart A—General Provisions

■ 3. Revise § 1003.100 to read as follows:

§ 1003.100 Basis and purpose.

(a) *Basis.* This part implements sections 1128(c), 1128A, 1140, 1819(b)(3)(B), 1819(g)(2)(A), 1857(g)(2)(A), 1860D–12(b)(3)(E), 1860D–31(i)(3), 1862(b)(3)(C), 1867(d)(1), 1876(i)(6), 1877(g), 1882(d), 1891(c)(1); 1903(m)(5), 1919(b)(3)(B), 1919(g)(2)(A), 1927(b)(3)(B), 1927(b)(3)(C), and 1929(i)(3) of the Social Security Act; sections 421(c) and 427(b)(2) of Pub. L. 99–660; and section 201(i) of Pub. L. 107–188 (42 U.S.C. 1320a–7(c), 1320a–7a, 1320b–10, 1395i–3(b)(3)(B), 1395i–3(g)(2)(A), 1395w–27(g)(2)(A), 1395w–112(b)(3)(E), 1395w–141(i)(3), 1395y(b)(3)(B), 1395dd(d)(1), 1395mm(i)(6), 1395nn(g), 1395ss(d), 1395bbb(c)(1), 1396b(m)(5), 1396r(b)(3)(B), 1396r(g)(2)(A), 1396r–7(b)(3)(B), 1396r–7(b)(3)(C), 1396t(i)(3), 11131(c), 11137(b)(2), and 262a(i)).

(b) *Purpose.* This part—

(1) Provides for the imposition of civil money penalties and, as applicable, assessments and exclusions against persons who have committed an act or omission that violates one or more provisions of this part and

(2) Sets forth the appeal rights of persons subject to a penalty, assessment, and exclusion.

■ 4. Remove §§ 1003.102 through 1003.110, 1003.114, 1003.126 through 1003.129, and 1003.132 through 1003.135.

■ 5. Redesignate § 1003.101 as § 1003.110.

■ 6. Amend newly designated § 1003.110 by:

■ a. Removing the definitions “Act”, “Adverse effect”, “ALJ”, “CMS”, “Department”, “Exclusion”, “Inspector General”, “Item or service”, “Medicaid”, “Medicare”, “Secretary”, “State”, “State health care program”, and “Transitional assistance”.

■ b. Revising the definitions of “Assessment”, “Claim”, “Contracting organization”, “Enrollee”, “Medical malpractice claim or action”, “Participating hospital”, “Penalty”, “Physician incentive plan”, “Responsible physician”, “Select agents and toxins”, and “Should know, or should have known”, “Social Services Block Grant Program”, and “Timely basis”.

■ c. Adding the definitions of “Items and services or items or services”, “Knowingly”, “Material”, “Non-separately-billable item or service”, “Overpayment”, “Reasonable request”, “Responsible Official”, “Select Agent Program”, “Separately billable item or service” in alphabetical order.

■ d. Amending the definition “Remuneration” by removing “as set forth in § 1003.102(b)(13) of this part,” and by adding after “Remuneration,” “for purposes of § 1003.1000(a) of this part,”.

The revisions and additions read as follows:

§ 1003.110 Definitions.

* * * * *

Assessment means the amounts described in this part and includes the plural of that term.

Claim means an application for payment for an item or service under a Federal health care program.

* * * * *

Contracting organization means a public or private entity, including a health maintenance organization, Medicare Advantage Plan, Prescription Drug Plan sponsor, or other organization that has contracted with the Department or a State to furnish services to Medicare or Medicaid beneficiaries pursuant to sections 1857, 1860D–12, 1876(b), or 1903(m) of the Act.

Enrollee means an individual who is eligible for Medicare or Medicaid and who enters into an agreement to receive services from a contracting organization.

* * * * *

Items and services or items or services includes without limitation, any item, device, drug, biological, supply, or service (including management or administrative services), including, but not limited to, those that are listed in an itemized claim for program payment or a request for payment; for which payment is included in any Federal or

State health care program reimbursement method, such as a prospective payment system or managed care system; or that are, in the case of a claim based on costs, required to be entered in a cost report, books of account, or other documents supporting the claim (whether or not actually entered).

Knowingly means that a person, with respect to an act, has actual knowledge of the act, acts in deliberate ignorance of the act, or acts in reckless disregard of the act, and that no proof of specific intent to defraud is required.

Material means having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property.

* * * * *

Medical malpractice claim or action means a written complaint or claim demanding payment based on a physician’s, dentist’s, or other health care practitioner’s provision of, or failure to provide, health care services and includes the filing of a cause of action based on the law of tort brought in any State or Federal court or other adjudicative body.

* * * * *

Non-separately-billable item or service means an item or service that is a component of, or otherwise contributes to the provision of, an item or a service, but is not itself a separately billable item or service.

Overpayment means any funds that a person receives or retains under Title XVIII or XIX to which the person, after applicable reconciliation, is not entitled under such title.

Participating hospital means either a hospital or a critical access hospital as defined in section 1861(mm)(1) of the Act that has entered into a Medicare provider agreement under section 1866 of the Act.

Penalty means the amount described in this part and includes the plural of that term.

* * * * *

Physician incentive plan means any compensation arrangement between a contracting organization and a physician or physician group that may directly or indirectly have the effect of reducing or limiting services provided with respect to enrollees in the organization.

* * * * *

Reasonable request, with respect to § 1003.200(b)(10), means a written request, signed by a designated representative of the OIG and made by a properly identified agent of the OIG during reasonable business hours. The request will include a statement of the

authority for the request, the person’s rights in responding to the request, the definition of “reasonable request” and “failure to grant timely access” under part 1003, the deadline by which the OIG requests access, and the amount of the civil money penalty or assessment that could be imposed and the effective date, length, and scope and effect of the exclusion that would be imposed for failure to comply with the request, and the earliest date that a request for reinstatement would be considered.

* * * * *

Responsible Official means the individual designated pursuant to 42 CFR part 73 to serve as the Responsible Official for the person holding a certificate of registration to possess, use, or transfer select agents or toxins.

Responsible physician means a physician who is responsible for the examination, treatment, or transfer of an individual who comes to a participating hospital’s emergency department requesting examination or treatment, including any physician who is on-call for the care of such individual and fails or refuses to appear within a reasonable time at such hospital to provide services relating to the examination, treatment, or transfer of such individual.

Responsible physician also includes a physician who is responsible for the examination or treatment of individuals at hospitals with specialized capabilities or facilities, as provided under section 1867(g) of the Act, including any physician who is on-call for the care of such individuals and refuses to accept an appropriate transfer or fails or refuses to appear within a reasonable time to provide services related to the examination or treatment of such individuals.

* * * * *

Select Agent Program means activities relating to the possession, use, and transfer of select agents and toxins as regulated by section 351A of the Public Health Service Act and 42 CFR part 73.

Select agents and toxins is defined consistent with the definition of “select agent and/or toxin” and “overlap select agent and/or toxin” as set forth in 42 CFR part 73.

Separately billable item or service means an item or service for which an identifiable payment may be made under a Federal health care program, e.g., an itemized claim or a payment under a prospective payment system or other reimbursement methodology.

Should know, or should have known, means that a person, with respect to information, either acts in deliberate ignorance of the truth or falsity of the information or acts in reckless disregard

of the truth or falsity of the information. For purposes of this definition, no proof of specific intent to defraud is required.

Social Services Block Grant Program means the program authorized under Title XX of the Act.

* * * * *

Timely basis means, in accordance with § 1003.300(a) of this part, the 60-day period from the time the prohibited amounts are collected by the individual or the entity.

* * * * *

■ 7. Add § 1003.120, 1003.130, 1003.140, 1003.150, and 1003.160 to subpart A to read as follows:

§ 1003.120 Liability for penalties and assessments.

(a) In any case when it is determined that more than one person was responsible for a violation described in this part, each such person may be held liable for the penalty prescribed by this part.

(b) In any case when it is determined that more than one person was responsible for a violation described in this part, an assessment may be imposed, when authorized, against any one such person or jointly and severally against two or more such persons, but the aggregate amount of the assessments collected may not exceed the amount that could be assessed if only one person was responsible.

(c) Under this part, a principal is liable for penalties and assessments for the actions of his or her agent acting within the scope of his or her agency. This provision does not limit the underlying liability of the agent.

§ 1003.130 Assessments.

The assessment in this part is in lieu of damages sustained by the Department or a State agency because of the violation.

§ 1003.140 Determinations regarding the amount of penalties and assessments and the period of exclusion.

(a) Except as otherwise provided in this part, in determining the amount of any penalty or assessment or the period of exclusion in accordance with this part, the OIG will consider the following factors—

(1) The nature and circumstances of the violation;

(2) The degree of culpability of the person against whom a civil money penalty, assessment, or exclusion is proposed. It should be considered an aggravating circumstance if the respondent had a greater level of knowledge than the minimum level of knowledge required to establish liability (e.g., for a provision that establishes

liability if the respondent “knew or should have known” a claim was false or fraudulent, it will be an aggravating circumstance if the respondent had actual knowledge the claim was false or fraudulent). It should be a mitigating circumstance if the person took appropriate and timely corrective action in response to the violation. For purposes of this part, corrective action must include disclosing the violation to the OIG through the Self-Disclosure Protocol and fully cooperating with the OIG’s review and resolution of such disclosure;

(3) The history of prior offenses. Aggravating circumstances include, if at any time prior to the violation, the person—or in the case of an entity, the entity itself; any individual who had a direct or indirect ownership or control interest (as defined in section 1124(a)(3) of the Act) in a sanctioned entity at the time the violation occurred and who knew, or should have known, of the violation; or any individual who was an officer or a managing employee (as defined in section 1126(b) of the Act) of such an entity at the time the violation occurred—was held liable for criminal, civil, or administrative sanctions in connection with a program covered by this part or in connection with the delivery of a health care item or service;

(4) *Other wrongful conduct.* Aggravating circumstances include proof that the person—or in the case of an entity, the entity itself; any individual who had a direct or indirect ownership or control interest (as defined in section 1124(a)(3) of the Act) in a sanctioned entity at the time the violation occurred and who knew, or should have known, of the violation; or any individual who was an officer or a managing employee (as defined in section 1126(b) of the Act) of such an entity at the time the violation occurred—engaged in wrongful conduct, other than the specific conduct upon which liability is based, relating to a government program or in connection with the delivery of a health care item or service. The statute of limitations governing civil money penalty proceedings will not apply to proof of other wrongful conduct as an aggravating circumstance; and

(5) *Such other matters as justice may require.* Other circumstances of an aggravating or mitigating nature should be considered if, in the interests of justice, they require either a reduction or an increase in the penalty, assessment, or period of exclusion to achieve the purposes of this part.

(b)(1) After determining the amount of any penalty and assessment in accordance with this part, the OIG

considers the ability of the person to pay the proposed civil money penalty or assessment. The person shall provide, in a time and manner requested by the OIG, sufficient financial documentation, including audited financial statements, tax returns, and financial disclosure statements, deemed necessary by the OIG to determine the person’s ability to pay.

(2) If the person requests a hearing in accordance with 42 CFR 1005.2, the only financial documentation subject to review is that which the person provided to the OIG during the administrative process, unless the ALJ finds that extraordinary circumstances prevented the person from providing the financial documentation to the OIG in the time and manner requested by the OIG prior to the hearing request.

(c) In determining the amount of any penalty and assessment to be imposed under this part the following circumstances are also to be considered—

(1) If there are substantial or several mitigating circumstances, the aggregate amount of the penalty and assessment should be set at an amount sufficiently below the maximum permitted by this part to reflect that fact.

(2) If there are substantial or several aggravating circumstances, the aggregate amount of the penalty and assessment should be set at an amount sufficiently close to or at the maximum permitted by this part to reflect that fact.

(3) Unless there are extraordinary mitigating circumstances, the aggregate amount of the penalty and assessment should not be less than double the approximate amount of damages and costs (as defined by paragraph (e)(2) of this section) sustained by the United States, or any State, as a result of the violation.

(4) The presence of any single aggravating circumstance may justify imposing a penalty and assessment at or close to the maximum even when one or more mitigating factors are present.

(d) In determining whether to exclude a person under this part, where there are aggravating circumstances, the person should be excluded.

(e)(1) The standards set forth in this section are binding, except to the extent that their application would result in imposition of an amount that would exceed limits imposed by the United States Constitution.

(2) The amount imposed will not be less than the approximate amount required to fully compensate the United States, or any State, for its damages and costs, tangible and intangible, including, but not limited to, the costs attributable

to the investigation, prosecution, and administrative review of the case.

(3) Nothing in this part limits the authority of the Department or the OIG to settle any issue or case as provided by § 1003.1530 or to compromise any penalty and assessment as provided by § 1003.1550.

(4) Penalties, assessments, and exclusions imposed under this part are in addition to any other penalties, assessments, or other sanctions prescribed by law.

§ 1003.150 Delegation of authority.

The OIG is delegated authority from the Secretary to impose civil money penalties and, as applicable, assessments and exclusions against any person who has violated one or more provisions of this part. The delegation of authority includes all powers to impose civil monetary penalties, assessments, and exclusion under section 1128A of the Act.

§ 1003.160 Waiver of exclusion.

(a) The OIG will consider a request from the administrator of a Federal health care program for a waiver of an exclusion imposed under this part as set forth in paragraph (b) of this section. The request must be in writing and from an individual directly responsible for administering the Federal health care program.

(b) If the OIG subsequently obtains information that the basis for a waiver no longer exists, the waiver will cease and the person will be excluded from the Federal health care programs for the remainder of the exclusion period, measured from the time the exclusion would have been imposed if the waiver had not been granted.

(c) The OIG will notify the administrator of the Federal health care program whether his or her request for a waiver has been granted or denied.

(d) If a waiver is granted, it applies only to the program(s) for which waiver is requested.

(e) The decision to grant, deny, or rescind a waiver is not subject to administrative or judicial review.

■ 8. Add subparts B through F to read as follows:

Subpart B—CMPs, Assessments, and Exclusions for False or Fraudulent Claims and Other Similar Misconduct

Sec.

1003.200 Basis for civil money penalties, assessments, and exclusions.

1003.210 Amount of penalties and assessments.

1003.220 Determinations regarding the amount of penalties and assessments and the period of exclusion.

Subpart C—CMPs, Assessments, and Exclusions for Anti-Kickback and Physician Self-Referral Violations

1003.300 Basis for civil money penalties, assessments, and exclusions.

1003.310 Amount of penalties and assessments.

1003.320 Determinations regarding the amount of penalties and assessments and the period of exclusion.

Subpart D—CMPs and Assessments for Contracting Organization Misconduct

1003.400 Basis for civil money penalties and assessments.

1003.410 Amount of penalties and assessments.

1003.420 Determinations regarding the amount of penalties and assessments.

Subpart E—CMPs and Exclusions for EMTALA Violations

1003.500 Basis for civil money penalties and exclusions.

1003.510 Amount of penalties.

1003.520 Determinations regarding the amount of penalties and the period of exclusion.

Subpart F—CMPs for Section 1140 Violations

1003.600 Basis for civil money penalties.

1003.610 Amount of penalties.

1003.620 Determinations regarding the amount of penalties.

Subpart B—CMPs, Assessments, and Exclusions for False or Fraudulent Claims and Other Similar Misconduct

§ 1003.200 Basis for civil money penalties, assessments, and exclusions.

(a) The OIG may impose a penalty, assessment, and an exclusion against any person who it determines has knowingly presented, or caused to be presented, a claim that was for—

(1) An item or service that the person knew, or should have known, was not provided as claimed, including a claim that was part of a pattern or practice of claims based on codes that the person knew, or should have known, would result in greater payment to the person than the code applicable to the item or service actually provided;

(2) An item or service for which the person knew, or should have known, that the claim was false or fraudulent;

(3) An item or service furnished during a period in which the person was excluded from participation in the Federal health care program to which the claim was made;

(4) A physician's services (or an item or service) for which the person knew, or should have known, that the individual who furnished (or supervised the furnishing of) the service—

(i) Was not licensed as a physician;

(ii) Was licensed as a physician, but such license had been obtained through a misrepresentation of material fact

(including cheating on an examination required for licensing); or

(iii) Represented to the patient at the time the service was furnished that the physician was certified in a medical specialty board when he or she was not so certified; or

(5) An item or service that a person knew, or should have known was not medically necessary, and which is part of a pattern of such claims.

(b) The OIG may impose a penalty; an exclusion; and, where authorized, an assessment against any person whom it determines—

(1) Has knowingly presented, or caused to be presented, a request for payment in violation of the terms of—

(i) An agreement to accept payments on the basis of an assignment under section 1842(b)(3)(B)(ii) of the Act;

(ii) An agreement with a State agency or other requirement of a State Medicaid plan not to charge a person for an item or service in excess of the amount permitted to be charged;

(iii) An agreement to be a participating physician or supplier under section 1842(h)(1) of the Act; or

(iv) An agreement in accordance with section 1866(a)(1)(G) of the Act not to charge any person for inpatient hospital services for which payment had been denied or reduced under section 1886(f)(2) of the Act;

(2) Has knowingly given, or caused to be given, to any person, in the case of inpatient hospital services subject to section 1886 of the Act, information that he or she knew, or should have known, was false or misleading and that could reasonably have been expected to influence the decision when to discharge such person or another person from the hospital;

(3) Is an individual and who is excluded from participating in a Federal health care program in accordance with sections 1128 or 1128A of the Act, and who—

(i) Knows, or should know, of the action constituting the basis for the exclusion and retains a direct or indirect ownership or control interest of 5 percent or more in an entity that participates in a Federal health care program or

(ii) Is an officer or a managing employee (as defined in section 1126(b) of the Act) of such entity;

(4) Arranges or contracts (by employment or otherwise) with an individual or entity that the person knows, or should know, is excluded from participation in Federal health care programs for the provision of items or services for which payment may be made under such a program;

(5) Has knowingly and willfully presented, or caused to be presented, a bill or request for payment for items and services furnished to a hospital patient for which payment may be made under a Federal health care program if that bill or request is inconsistent with an arrangement under section 1866(a)(1)(H) of the Act or violates the requirements for such an arrangement;

(6) Orders or prescribes a medical or other item or service during a period in which the person was excluded from a Federal health care program, in the case when the person knows, or should know, that a claim for such medical or other item or service will be made under such a program;

(7) Knowingly makes, or causes to be made, any false statement, omission, or misrepresentation of a material fact in any application, bid, or contract to participate or enroll as a provider of services or a supplier under a Federal health care program, including contracting organizations and entities that apply to participate as providers of services or suppliers in such contracting organizations;

(8) Knows of an overpayment and does not report and return the overpayment in accordance with section 1128J(d) of the Act;

(9) Knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim for payment for items and services furnished under a Federal health care program; or

(10) Fails to grant timely access to records, documents, and other material or data in any medium (including electronically stored information and any tangible thing), upon reasonable request, to the OIG, for the purpose of audits, investigations, evaluations, or other OIG statutory functions. Such failure to grant timely access means:

(i) Except when the OIG reasonably believes that the requested material is about to be altered or destroyed, the failure to produce or make available for inspection and copying the requested material upon reasonable request or to provide a compelling reason why they cannot be produced, by the deadline specified in the OIG's written request, and

(ii) When the OIG has reason to believe that the requested material is about to be altered or destroyed, the failure to provide access to the requested material at the time the request is made.

(c) The OIG may impose a penalty against any person who it determines, in accordance with this part, is a physician and who executes a document falsely by certifying that a Medicare beneficiary

requires home health services when the physician knows that the beneficiary does not meet the eligibility requirements in sections 1814(a)(2)(C) or 1835(a)(2)(A) of the Act.

(d) The OIG may impose a penalty against any person who it determines knowingly certifies, or causes another individual to certify, a material and false statement in a resident assessment pursuant to sections 1819(b)(3)(B) and 1919(b)(3)(B).

§ 1003.210 Amount of penalties and assessments.

(a) *Penalties.* (1) Except as provided in this section, the OIG may impose a penalty of not more than \$10,000 for each individual violation that is subject to a determination under this subpart.

(2) The OIG may impose a penalty of not more than \$15,000 for each person with respect to whom a determination was made that false or misleading information was given under § 1003.200(b)(2).

(3) The OIG may impose a penalty of not more than \$10,000 per day for each day that the prohibited relationship described in § 1003.200(b)(3) occurs.

(4) For each individual violation of § 1003.200(b)(4), the OIG may impose a penalty of not more than \$10,000—

(i) For each separately billable item or service provided, furnished, ordered, or prescribed by an excluded individual or entity, or

(ii) For each day the person employs, contracts with, or otherwise arranges for an excluded individual or entity to provide, furnish, order, or prescribe a non-separately-billable item or service.

(5) The OIG may impose a penalty of not more than \$2,000 for each bill or request for payment for items and services furnished to a hospital patient in violation of § 1003.200(b)(5).

(6) The OIG may impose a penalty of not more than \$50,000 for each false statement, omission, or misrepresentation of a material fact in violation of § 1003.200(b)(7).

(7) The OIG may impose a penalty of not more than \$50,000 for each false record or statement in violation of § 1003.200(b)(9).

(8) The OIG may impose a penalty of not more than \$10,000 per day for each overpayment that is not reported and returned in accordance with section 1128J(d) of the Act in violation of § 1003.200(b)(8).

(9) The OIG may impose a penalty of not more than \$15,000 for each day of failure to grant timely access in violation of § 1003.200(b)(10).

(10) For each false certification in violation of § 1003.200(c), the OIG may impose a penalty of not more than the greater of—

(i) \$5,000; or

(ii) Three times the amount of Medicare payments for home health services that are made with regard to the false certification of eligibility by a physician, as prohibited by section 1814(a)(2)(C) or 1835(a)(2)(A) of the Act.

(11) For each false certification in violation of § 1003.200(d), the OIG may impose a penalty of not more than—

(i) \$1,000 with respect to an individual who willfully and knowingly falsely certifies a material and false statement in a resident assessment; and

(ii) \$5,000 with respect to an individual who willfully and knowingly causes another individual to falsely certify a material and false statement in a resident assessment.

(b) *Assessments.* (1) Except for violations of § 1003.200(b)(4), (5), and (7), and § 1003.200(c) and (d), the OIG may impose an assessment for each individual violation of § 1003.200, of not more than 3 times the amount for each item or service wrongfully claimed.

(2) For violations of § 1003.200(b)(4), the OIG may impose an assessment of not more than 3 times—

(i) The amount claimed for each separately billable item or service provided, furnished, ordered, or prescribed by an excluded individual or entity or

(ii) The total costs (including salary, benefits, taxes, and other money or items of value) related to the excluded individual or entity incurred by the person that employs, contracts with, or otherwise arranges for an excluded individual or entity to provide, furnish, order, or prescribe a non-separately-billable item or service.

(3) For violations of § 1003.200(b)(7), the OIG may impose an assessment of not more than 3 times the total amount claimed for each item or service for which payment was made based upon the application containing the false statement, omission, or misrepresentation of material fact.

§ 1003.220 Determinations regarding the amount of penalties and assessments and the period of exclusion.

In considering the factors listed in § 1003.140—

(a) It should be considered a mitigating circumstance if all the items or services or violations included in the action brought under this part were of the same type and occurred within a short period of time, there were few such items or services or violations, and the total amount claimed or requested for such items or services was less than \$5,000.

(b) Aggravating circumstances include—

(1) The violations were of several types or occurred over a lengthy period of time;

(2) There were many such items or services or violations (or the nature and circumstances indicate a pattern of claims or requests for payment for such items or services or a pattern of violations);

(3) The amount claimed or requested for such items or services, or the amount of the overpayment was \$15,000 or more;

(4) The violation resulted, or could have resulted, in patient harm, premature discharge, or a need for additional services or subsequent hospital admission; or

(5) The amount or type of financial, ownership, or control interest or the degree of responsibility a person has in an entity was substantial with respect to an action brought under § 1003.200(b)(3).

Subpart C—CMPs, Assessments, and Exclusions for Anti-Kickback and Physician Self-Referral Violations

§ 1003.300 Basis for civil money penalties, assessments, and exclusions.

The OIG may impose a penalty, an assessment, and an exclusion against any person who it determines in accordance with this part—

(a) Has not refunded on a timely basis, as defined in § 1003.110, amounts collected as a result of billing an individual, third party payer, or other entity for a designated health service furnished pursuant to a prohibited referral as described in § 411.353 of this title.

(b) Is a physician or other person that enters into any arrangement or scheme (such as a cross-referral arrangement) that the physician or other person knows, or should know, has a principal purpose of ensuring referrals by the physician to a particular person that, if the physician directly made referrals to such person, would be in violation of the prohibitions of § 411.353 of this title.

(c) Has knowingly presented, or caused to be presented, a claim that is for a payment that such person knows, or should know, may not be made under § 411.353 of this title;

(d) Has violated section 1128B(b) of the Act by unlawfully offering, paying, soliciting, or receiving remuneration to induce or in return for the referral of business paid for, in whole or in part, by Medicare, Medicaid, or other Federal health care programs.

§ 1003.310 Amount of penalties and assessments.

(a) *Penalties.* The OIG may impose a penalty of not more than—

(1) \$15,000 for each claim or bill for a designated health service, as defined in § 411.351 of this title, that is subject to a determination under § 1003.300(a) or (c);

(2) \$100,000 for each arrangement or scheme that is subject to a determination under § 1003.300(b); and

(3) \$50,000 for each offer, payment, solicitation, or receipt of remuneration that is subject to a determination under § 1003.300(d).

(b) *Assessments.* The OIG may impose an assessment of not more than 3 times—

(1) The amount claimed for each designated health service that is subject to a determination under § 1003.300(a), (b), or (c).

(2) The total remuneration offered, paid, solicited, or received that is subject to a determination under § 1003.300(d). Calculation of the total remuneration for purposes of an assessment shall be without regard to whether a portion of such remuneration was offered, paid, solicited, or received for a lawful purpose.

§ 1003.320 Determinations regarding the amount of penalties and assessments and the period of exclusion.

In considering the factors listed in § 1003.140:

(a) It should be considered a mitigating circumstance if all the items, services, or violations included in the action brought under this part were of the same type and occurred within a short period of time; there were few such items, services, or violations; and the total amount claimed or requested for such items or services was less than \$5,000.

(b) Aggravating circumstances include—

(1) The violations were of several types or occurred over a lengthy period of time;

(2) There were many such items, services, or violations (or the nature and circumstances indicate a pattern of claims or requests for payment for such items or services or a pattern of violations);

(3) The amount claimed or requested for such items or services or the amount of the remuneration was \$15,000 or more; or

(4) The violation resulted, or could have resulted, in harm to the patient, a premature discharge, or a need for additional services or subsequent hospital admission.

Subpart D—CMPs and Assessments for Contracting Organization Misconduct

§ 1003.400 Basis for civil money penalties and assessments.

(a) *All contracting organizations.* The OIG may impose a penalty against any contracting organization that—

(1) Fails substantially to provide an enrollee with medically necessary items and services that are required (under the Act, applicable regulations, or contract) to be provided to such enrollee and the failure adversely affects (or has the substantial likelihood of adversely affecting) the enrollee;

(2) Imposes a premium on an enrollee in excess of the amounts permitted under the Act;

(3) Engages in any practice that would reasonably be expected to have the effect of denying or discouraging enrollment by beneficiaries whose medical condition or history indicates a need for substantial future medical services, except as permitted by the Act;

(4) Misrepresents or falsifies information furnished to a person;

(5) Misrepresents or falsifies information furnished to the Secretary or a State, as applicable;

(6) Fails to comply with the requirements of 42 CFR 417.479(d) through (i) for Medicare and 42 CFR 417.479(d) through (g) and (i) for Medicaid regarding certain prohibited incentive payments to physicians; or

(7) Fails to comply with applicable requirements of the Act regarding prompt payment of claims.

(b) *All Medicare contracting organizations.* The OIG may impose a penalty against any contracting organization with a contract under section 1857, 1860D–12, or 1876 of the Act that—

(1) Acts to expel or to refuse to reenroll a beneficiary in violation of the Act or

(2) Employs or contracts with a person excluded, under section 1128 or 1128A of the Act, from participation in Medicare for the provision of health care, utilization review, medical social work, or administrative services, or employs or contracts with any entity for the provision of such services (directly or indirectly) through an excluded person.

(c) *Medicare Advantage and Part D contracting organizations.* The OIG may impose a penalty, and for § 1003.400(c)(4) or (c)(5), an assessment, against a contracting organization with a contract under section 1857 or 1860D–12 of the Act that:

(1) Enrolls an individual without the individual's (or his or her designee's)

prior consent, except as provided under subparagraph (C) or (D) of section 1860D–1(b)(1) of the Act;

(2) Transfers an enrollee from one plan to another without the individual's (or his or her designee's) prior consent;

(3) Transfers an enrollee solely for the purpose of earning a commission;

(4) Fails to comply with marketing restrictions described in subsection (h) or (j) of section 1851 of the Act or applicable implementing regulations or guidance; or

(5) Employs or contracts with any person who engages in the conduct described in paragraphs (a) through (c) of this section.

(d) *Medicare Advantage contracting organizations.* The OIG may impose a penalty against a contracting organization with a contract under section 1857 of the Act that fails to comply with the requirements of section 1852(j)(3) or 1852(k)(2)(A)(ii) of the Act.

(e) *Medicaid contracting organizations.* The OIG may impose a penalty against any contracting organization with a contract under section 1903(m) of the Act that acts to discriminate among individuals in violation of the Act, including expulsion or refusal to reenroll an individual or engaging in any practice that would reasonably be expected to have the effect of denying or discouraging enrollment by eligible individuals with the contracting organization whose medical condition or history indicates a need for substantial future medical services.

§ 1003.410 Amount of penalties and assessments.

(a) *Penalties.* (1) The OIG may impose a penalty of up to \$25,000 for each individual violation under § 1001.400, except as provided in this section.

(2) The OIG may impose a penalty of up to \$100,000 for each individual violation under § 1003.400(a)(3), (a)(5), or (e).

(b) *Additional penalties.* In addition to the penalties described in paragraph (a) of this section, the OIG may impose—

(1) An additional penalty equal to double the amount of excess premium charged by the contracting organization for each individual violation of § 1003.400(a)(2). The excess premium amount will be deducted from the penalty and returned to the enrollee.

(2) An additional \$15,000 penalty for each individual expelled or not enrolled in violation of § 1003.400(a)(3) or (e).

(c) *Assessments.* The OIG may impose an assessment against a contracting organization with a contract under section 1857 or 1860D–12 of the Act

(Medicare Advantage or Part D) of not more than the amount claimed in violation of § 1003.400(a)(4) or (a)(5) on the basis of the misrepresentation or falsified information involved.

(d) The OIG may impose a penalty or, when applicable, an assessment, against a contracting organization with a contract under section 1857 or 1860D–12 of the Act (Medicare Advantage or Part D) if any of its employees, agents, or contracting providers or suppliers engages in any of the conduct described in § 1003.400(a) through (d).

§ 1003.420 Determinations regarding the amount of penalties and assessments.

In considering the factors listed in § 1003.140, aggravating circumstances include—

(a) Such violations were of several types or occurred over a lengthy period of time;

(b) There were many such violations (or the nature and circumstances indicate a pattern of incidents);

(c) The amount of money, remuneration, damages, or tainted claims involved in the violation was \$15,000 or more; or

(d) Patient harm, premature discharge, or a need for additional services or subsequent hospital admission resulted, or could have resulted, from the incident; and

(e) The contracting organization knowingly or routinely engaged in any prohibited practice that acted as an inducement to reduce or limit medically necessary services provided with respect to a specific enrollee in the organization.

Subpart E—CMPs and Exclusions for EMTALA Violations

§ 1003.500 Basis for civil money penalties and exclusions.

(a) The OIG may impose a penalty against any participating hospital with an emergency department or specialized capabilities or facilities for each negligent violation of section 1867 of the Act or § 489.24 of this title.

(b) The OIG may impose a penalty against any responsible physician for each—

(1) Negligent violation of section 1867 of the Act;

(2) Certification signed under section 1867(c)(1)(A) of the Act if the physician knew, or should have known, that the benefits of transfer to another facility did not outweigh the risks of such a transfer; or

(3) Misrepresentation made concerning an individual's condition or other information, including a hospital's obligations under section 1867 of the Act.

(c) The OIG may, in lieu of or in addition to any penalty available under this subpart, exclude any responsible physician that commits a gross and flagrant, or repeated, violation of this subpart from participation in Federal health care programs.

(d) For purposes of this subpart, a “gross and flagrant violation” is a violation that presents an imminent danger to the health, safety, or well-being of the individual who seeks examination and treatment or places that individual unnecessarily in a high-risk situation.

§ 1003.510 Amount of penalties.

The OIG may impose—

(a) Against each participating hospital, a penalty of not more than \$50,000 for each individual violation, except that if the participating hospital has fewer than 100 State-licensed, Medicare-certified beds on the date the penalty is imposed, the penalty will not exceed \$25,000 for each violation, and

(b) Against each responsible physician, a penalty of not more than \$50,000 for each individual violation.

§ 1003.520 Determinations regarding the amount of penalties and the period of exclusion.

In considering the factors listed in § 1003.140, aggravating circumstances include:

(a) Requesting proof of insurance, prior authorization, or a monetary payment prior to appropriately screening or initiating stabilizing treatment for an emergency medical condition, or requesting a monetary payment prior to stabilizing an emergency medical condition;

(b) Patient harm or unnecessary risk of patient harm, premature discharge, or a need for additional services or subsequent hospital admission resulted, or could have resulted, from the incident; or

(c) The individual presented to the hospital with a request for examination or treatment of a medical condition that was an emergency medical condition, as defined by § 489.24(b) of this title.

Subpart F—CMPs for Section 1140 Violations

§ 1003.600 Basis for civil money penalties.

(a) The OIG may impose a penalty against any person who it determines in accordance with this part has used the words, letters, symbols, or emblems as defined in paragraph (b) of this section in such a manner that such person knew, or should have known, would convey, or in a manner that reasonably could be interpreted or construed as conveying, the false impression that an

advertisement, a solicitation, or other item was authorized, approved, or endorsed by the Department or CMS or that such person or organization has some connection with or authorization from the Department or CMS.

(b) Civil money penalties may be imposed, regardless of the use of a disclaimer of affiliation with the United States Government, the Department, or its programs, for misuse of—

(1) The words “Department of Health and Human Services,” “Health and Human Services,” “Centers for Medicare & Medicaid Services,” “Medicare,” or “Medicaid” or any other combination or variations of such words;

(2) The letters “DHHS,” “HHS,” or “CMS,” or any other combination or variation of such letters; or

(3) A symbol or an emblem of the Department or CMS (including the design of, or a reasonable facsimile of the design of, the Medicare card, the check used for payment of benefits under Title II, or envelopes or other stationery used by the Department or CMS) or any other combination or variation of such symbols or emblems.

(c) Civil money penalties will not be imposed against any agency or instrumentality of a State, or political subdivision of the State, that uses any symbol or emblem or any words or letters that specifically identify that agency or instrumentality of the State or political subdivision.

§ 1003.610 Amount of penalties.

(a) The OIG may impose a penalty of not more than—

(1) \$5,000 for each individual violation resulting from the misuse of Departmental, CMS, or Medicare or Medicaid program words, letters, symbols, or emblems as described in § 1003.600(a) relating to printed media;

(2) \$5,000 for each individual violation in the case of such misuse related to an electronic message, Web page, or telemarketing solicitation;

(3) \$25,000 for each individual violation in the case of such misuse related to a broadcast or telecast.

(b) For purposes of this paragraph, a violation is defined as—

(1) In the case of a direct mailing solicitation or an advertisement, each separate piece of mail that contains one or more words, letters, symbols, or emblems related to a determination under § 1003.600(a);

(2) In the case of a printed solicitation or an advertisement, each reproduction, reprinting, or distribution of such item related to a determination under § 1003.600(a);

(3) In the case of a broadcast or telecast, each airing of a single

commercial or solicitation related to a determination under § 1003.600(a);

(4) In the case of electronic mail (email) messages, each separate email address that received the email message that contains one or more words, letters, symbols, or emblems related to a determination under § 1003.600(a);

(5) In the case of a Web page (such as an Internet site) accessed by a computer or other electronic means, each instance in which an individual views such Web page that contains one or more words, letters, symbols, or emblems related to a determination under § 1003.600(a); and

(6) In the case of a telemarketing solicitation, each individual unsolicited telephone call regarding the delivery of an item or service under Medicare or Medicaid related to a determination under § 1003.600(a).

§ 1003.620 Determinations regarding the amount of penalties.

(a) In considering the factors listed in § 1003.140, the following circumstances are to be considered—

(1) The nature and objective of the advertisement, solicitation, or other communication and the degree to which it had the capacity to deceive members of the public;

(2) The frequency and scope of the violation and whether a specific segment of the population was targeted; and

(3) The prior history of the individual, organization, or entity in its willingness or refusal to comply with informal requests to correct violations.

(b) The use of a disclaimer of affiliation with the United States Government, the Department, or its programs will not be considered as a mitigating factor in determining the amount of penalty in accordance with § 1003.600(a).

■ 9. Add and reserve subpart G to read as follows:

Subpart G—[Reserved]

■ 10. Add subparts H through M to read as follows:

Subpart H—CMPs for Adverse Action Reporting and Disclosure Violations

Sec.

1003.800 Basis for civil money penalties.

1003.810 Amount of penalties.

1003.820 Determinations regarding the amount of penalties.

Subpart I—CMPs for Select Agent Program Violations

1003.900 Basis for civil money penalties.

1003.910 Amount of penalties.

1003.920 Determinations regarding the amount of penalties.

Subpart J—CMPs, Assessments, and Exclusions for Beneficiary Inducement Violations

1003.1000 Basis for civil money penalties, assessments, and exclusions.

1003.1010 Amount of penalties and assessments.

1003.1020 Determinations regarding the amount of penalties and assessments and the period of exclusion.

Subpart K—CMPs for the Sale of Medicare Supplemental Policies.

1003.1100 Basis for civil money penalties.

1003.1110 Amount of penalties.

1003.1120 Determinations regarding the amount of penalties.

Subpart L—CMPs for Drug Price Reporting

1003.1200 Basis for civil money penalties.

1003.1210 Amount of penalties.

1003.1220 Determinations regarding the amount of penalties.

Subpart M—CMPs for Notifying a Skilled Nursing Facility, Nursing Facility, Home Health Agency, or Community Care Setting of a Survey

1003.1300 Basis for civil money penalties.

1003.1310 Amount of penalties.

1003.1320 Determinations regarding the amount of penalties.

Subpart H—CMPs for Adverse Action Reporting and Disclosure Violations

§ 1003.800 Basis for civil money penalties.

The OIG may impose a penalty against any person (including an insurance company) who it determines—

(a) Fails to report information concerning—

(1) A payment made under an insurance policy, self-insurance, or otherwise for the benefit of a physician, dentist, or other health care practitioner in settlement of, or in satisfaction in whole or in part of, a medical malpractice claim or action or a judgment against such a physician, dentist, or other practitioner in accordance with section 421 of Public Law 99–660 (42 U.S.C. 11131) and as required by regulations at 45 CFR part 60 or

(2) An adverse action required to be reported under section 1128E, as established by section 221 of Public Law 104–191.

(b) Improperly discloses, uses, or permits access to information reported in accordance with part B of Title IV of Public Law 99–660 (42 U.S.C. 11137) or regulations at 45 CFR part 60. (The disclosure of information reported in accordance with part B of Title IV in response to a subpoena or a discovery request is considered an improper disclosure in violation of section 427 of Public Law 99–660. However, disclosure or release by an entity of

original documents or underlying records from which the reported information is obtained or derived is not considered an improper disclosure in violation of section 427 of Pub. L. 99-660.)

§ 1003.810 Amount of penalties.

The OIG may impose a penalty of not more than—

(a) \$11,000 for each payment for which there was a failure to report required information in accordance with § 1003.800(a)(1) or for each improper disclosure, use, or access to information in accordance with a determination under § 1003.800(b); and

(b) \$25,000 against a health plan for each failure to report information on an adverse action required to be reported in accordance with section 1128E of the Act and § 1003.800(a)(2).

§ 1003.820 Determinations regarding the amount of penalties.

In determining the amount of any penalty in accordance with this subpart, the OIG will consider the factors listed in § 1003.140.

Subpart I—CMPs for Select Agent Program Violations

§ 1003.900 Basis for civil money penalties.

The OIG may impose a penalty against any person who it determines in accordance with this part is involved in the possession or use in the United States, receipt from outside the United States or transfer within the United States, of select agents and toxins in violation of 42 CFR part 73 as determined by the HHS Secretary, in accordance with sections 351A(b) and (c) of the Public Health Service Act.

§ 1003.910 Amount of penalties.

For each individual violation of section 351A(b) or (c) of the Public Health Service Act or 42 CFR part 73, the OIG may impose a penalty of not more than \$250,000 in the case of an individual, and not more than \$500,000 in the case of any other person.

§ 1003.920 Determinations regarding the amount of penalties.

In considering the factors listed in § 1003.140, aggravating circumstances include:

(a) The Responsible Official participated in or knew, or should have known, of the violation;

(b) The violation was a contributing factor, regardless of proportionality, to an unauthorized individual's access to or possession of a select agent or toxin, an individual's exposure to a select agent or toxin, or the unauthorized removal of a select agent or toxin from

the person's physical location as identified on the person's certificate of registration; or

(c) The person previously received a statement of deficiency from the Department or the Department of Agriculture for the same or substantially similar conduct.

Subpart J—CMPs, Assessments, and Exclusions for Beneficiary Inducement Violations

§ 1003.1000 Basis for civil money penalties, assessments, and exclusions.

(a) The OIG may impose a penalty, an assessment, and an exclusion against any person who it determines offers or transfers remuneration (as defined in § 1003.110) to any individual eligible for benefits under Medicare or a State health care program that such person knows, or should know, is likely to influence such individual to order or to receive from a particular provider, practitioner, or supplier, any item or service for which payment may be made, in whole or in part, under Medicare or a State health care program.

(b) The OIG may impose a penalty against any person who it determines offered any financial or other incentive for an individual entitled to benefits under Medicare not to enroll, or to terminate enrollment, under a group health plan or a large group health plan that would, in the case of such enrollment, be a primary plan as defined in section 1862(b)(2)(A) of the Act.

§ 1003.1010 Amount of penalties and assessments.

The OIG may impose a penalty of not more than—

(a) \$10,000 for each individual violation of § 1003.1000(a) and an assessment of not more than 3 times the amount for each item or service wrongfully claimed; and

(b) \$5,000 for each individual violation of § 1003.1000(b).

§ 1003.1020 Determinations regarding the amount of penalties and assessments and the period of exclusion.

In determining the amount of any penalty or assessment or the period of exclusion under this subpart, the OIG will consider the factors listed in § 1003.140, as well as the amount of remuneration or the amount or nature of any other incentive.

Subpart K—CMPs for the Sale of Medicare Supplemental Policies

§ 1003.1100 Basis for civil money penalties.

The OIG may impose a penalty against any person who—

(a) Knowingly and willfully makes or causes to be made or induces or seeks to induce the making of any false statement or representation of a material fact with respect to—

(1) The compliance of any policy with the standards and requirements for Medicare supplemental policies set forth in section 1882(c) of the Act or in promulgating regulations, or

(2) The use of the emblem designed by the Secretary under section 1882(a) of the Act for use as an indication that a policy has received the Secretary's certification;

(b) Falsely assumes or pretends to be acting, or misrepresents in any way that he or she is acting, under the authority of or in association with Medicare or any Federal agency, for the purpose of selling or attempting to sell insurance, or in such pretended character demands, or obtains money, paper, documents, or anything of value;

(c) Knowingly, directly, or through his or her agent, mails or causes to be mailed any matter for the advertising, solicitation, or offer for sale of a Medicare supplemental policy, or the delivery of such a policy, in or into any State in which such policy has not been approved by the State commissioner or superintendent of insurance;

(d) Issues or sells to any individual entitled to benefits under Part A or enrolled under Part B of title XVIII of the Act—

(1) A health insurance policy with knowledge that the policy duplicates health benefits to which the individual is otherwise entitled under title XVIII or title XIX of the Act,

(2) A health insurance policy (other than a Medicare supplemental policy) with knowledge that the policy duplicates health benefits to which the individual is otherwise entitled, other than benefits to which the individual is entitled under a requirement of State or Federal law,

(3) In the case of an individual not electing a Part C plan, a Medicare supplemental policy with knowledge that the individual is entitled to benefits under another Medicare supplemental policy, or

(4) In the case of an individual electing a Part C plan, a Medicare supplemental policy with knowledge that the policy duplicates health benefits to which the individual is otherwise entitled under the Part C plan or under another Medicare supplemental policy;

(e) Issues or sells a health insurance policy (other than a policy described in section 1882(d)(3)(A)(vi)(III)) to any individual entitled to benefits under Part A or enrolled under Part B of title

XVIII of the Act who is applying for a health insurance policy and fails to furnish the appropriate disclosure statement described in section 1882(d)(3)(A)(vii); or

(f) Issues or sells a Medicare supplemental policy to any individual eligible for benefits under Part A or enrolled under Part B of title XVIII of the Act without obtaining the written statement or the written acknowledgment described in section 1882(d)(3)(B) of the Act.

§ 1003.1110 Amount of penalties.

The OIG may impose a penalty of not more than—

(a) \$5,000 for each individual violation of § 1003.1100(a), (b), or (c).

(b) \$25,000 for each individual violation of § 1003.1100(d), (e), or (f) by a seller who is also the issuer of the policy; and

(c) \$15,000 for each individual violation of § 1003.1100(d), (e), or (f) by a seller who is not the issuer of the policy.

§ 1003.1120 Determinations regarding the amount of penalties.

In determining the amount of the penalty in accordance with this subpart, the OIG will consider the factors listed in § 1003.140.

Subpart L—CMPs for Drug Price Reporting

§ 1003.1200 Basis for civil money penalties.

The OIG may impose a penalty against—

(a) Any wholesaler, manufacturer, or direct seller of a covered outpatient drug that—

(1) Refuses a request for information by, or

(2) Knowingly provides false information to, the Secretary about charges or prices in connection with a survey being conducted pursuant to section 1927(b)(3)(B) of the Act; and

(b) Any manufacturer with an agreement under section 1927 of the Act that—

(1) Fails to provide any information required by section 1927(b)(3)(A) of the Act by the deadlines specified therein, or

(2) Knowingly provides any item information required by section 1927(b)(3)(A) or (B) of the Act that is false.

§ 1003.1210 Amount of penalties.

The OIG may impose a penalty of not more than—

(a) \$100,000 for each individual violation of § 1003.1200(a) or § 1003.1200(b)(2); and

(b) \$10,000 for each day that such information has not been provided in violation of § 1003.1200(b)(1).

§ 1003.1220 Determinations regarding the amount of penalties.

In determining the amount of the penalty in accordance with this subpart, the OIG will consider the factors listed in § 1003.140.

Subpart M—CMPs for Notifying a Skilled Nursing Facility, Nursing Facility, Home Health Agency, or Community Care Setting of a Survey

§ 1003.1300 Basis for civil money penalties.

The OIG may impose a penalty against any individual who notifies, or causes to be notified, a skilled nursing facility, nursing facility, home health agency, a community care setting, of the time or date on which a survey pursuant to sections 1819(g)(2)(A), 1919(g)(2)(A), 1891(c)(1), or 1929(i) of the Act is scheduled to be conducted.

§ 1003.1310 Amount of penalties.

The OIG may impose a penalty of not more than \$2,000 for each individual violation of § 1003.1300.

§ 1003.1320 Determinations regarding the amount of penalties.

In determining the amount of the penalty in accordance with this subpart, the OIG will consider the factors listed in § 1003.140.

■ 11. Add and reserve subpart N to read as follows:

Subpart N—[Reserved]

■ 12. Add subpart O to read as follows:

Subpart O—Procedures for the Imposition of CMPs, Assessments, and Exclusions

Sec.

1003.1500 Notice of proposed determination.

1003.1510 Failure to request a hearing.

1003.1520 Collateral estoppel.

1003.1530 Settlement.

1003.1540 Judicial review.

1003.1550 Collection of penalties and assessments.

1003.1560 Notice to other agencies.

1003.1570 Limitations.

1003.1580 Statistical sampling.

1003.1590 Effect of exclusion.

1003.1600 Reinstatement.

Subpart O—Procedures for the Imposition of CMPs, Assessments, and Exclusions

§ 1003.1500 Notice of proposed determination.

(a) If the OIG proposes a penalty and, when applicable, an assessment, or proposes to exclude a respondent from participation in all Federal health care

programs, as applicable, in accordance with this part, the OIG must serve on the respondent, in any manner authorized by Rule 4 of the Federal Rules of Civil Procedure, written notice of the OIG's intent to impose a penalty, an assessment, and an exclusion, as applicable. The notice will include—

(1) Reference to the statutory basis for the penalty, assessment, and exclusion;

(2) A description of the violation for which the penalty, assessment, and exclusion are proposed (except in cases when the OIG is relying upon statistical sampling in accordance with

§ 1003.1580, in which case the notice shall describe those claims and requests for payment constituting the sample upon which the OIG is relying and will briefly describe the statistical sampling technique used by the OIG);

(3) The reason why such violation subjects the respondent to a penalty, an assessment, and an exclusion,

(4) The amount of the proposed penalty and assessment, and the length of the period of proposed exclusion (where applicable);

(5) Any factors and circumstances described in this part that were considered when determining the amount of the proposed penalty and assessment and the length of the period of exclusion;

(6) Instructions for responding to the notice, including—

(i) A specific statement of the respondent's right to a hearing and

(ii) A statement that failure to request a hearing within 60 days permits the imposition of the proposed penalty, assessment, and exclusion without right of appeal; and

(7) In the case of a notice sent to a respondent who has an agreement under section 1866 of the Act, the notice also indicates that the imposition of an exclusion may result in the termination of the respondent's provider agreement in accordance with section 1866(b)(2)(C) of the Act.

(b) Any person upon whom the OIG has proposed the imposition of a penalty, an assessment, or an exclusion may appeal such proposed penalty, assessment, or exclusion to the DAB in accordance with 42 CFR 1005.2. The provisions of 42 CFR part 1005 govern such appeals.

(c) If the respondent fails, within the time period permitted, to exercise his or her right to a hearing under this section, any exclusion, penalty, or assessment becomes final.

§ 1003.1510 Failure to request a hearing.

If the respondent does not request a hearing within 60 days after the notice prescribed by § 1003.1500(a) is received,

as determined by 42 CFR 1005.2(c), by the respondent, the OIG may impose the proposed penalty, assessment, and exclusion, or any less severe penalty, assessment, or exclusion. The OIG shall notify the respondent in any manner authorized by Rule 4 of the Federal Rules of Civil Procedure of any penalty, assessment, and exclusion that have been imposed and of the means by which the respondent may satisfy the judgment. The respondent has no right to appeal a penalty, an assessment, or an exclusion with respect to which he or she has not requested a hearing.

§ 1003.1520 Collateral estoppel.

(a) Where a final determination pertaining to the respondent's liability for acts that violate this part has been rendered in any proceeding in which the respondent was a party and had an opportunity to be heard, the respondent shall be bound by such determination in any proceeding under this part.

(b) In a proceeding under this part, a person is estopped from denying the essential elements of the criminal offense if the proceeding—

(1) Is against a person who has been convicted (whether upon a verdict after trial or upon a plea of guilty or nolo contendere) of a Federal crime charging fraud or false statements, and

(2) Involves the same transactions as in the criminal action.

§ 1003.1530 Settlement.

The OIG has exclusive authority to settle any issues or case without consent of the ALJ.

§ 1003.1540 Judicial review.

(a) Section 1128A(e) of the Act authorizes judicial review of a penalty, an assessment, or an exclusion that has become final. The only matters subject to judicial review are those that the respondent raised pursuant to 42 CFR 1005.21, unless the court finds that extraordinary circumstances existed that prevented the respondent from raising the issue in the underlying administrative appeal.

(b) A respondent must exhaust all administrative appeal procedures established by the Secretary or required by law before a respondent may bring an action in Federal court, as provided in section 1128A(e) of the Act, concerning any penalty, assessment, or exclusion imposed pursuant to this part.

(c) Administrative remedies are exhausted when a decision becomes final in accordance with 42 CFR 1005.21(j).

§ 1003.1550 Collection of penalties and assessments.

(a) Once a determination by the Secretary has become final, collection of any penalty and assessment will be the responsibility of CMS, except in the case of the Maternal and Child Health Services Block Grant Program, in which the collection will be the responsibility of the Public Health Service (PHS); in the case of the Social Services Block Grant program, in which the collection will be the responsibility of the Office of Human Development Services; and in the case of violations of subpart I, collection will be the responsibility of the Program Support Center (PSC).

(b) A penalty or an assessment imposed under this part may be compromised by the OIG and may be recovered in a civil action brought in the United States district court for the district where the claim was presented or where the respondent resides.

(c) The amount of penalty or assessment, when finally determined, or the amount agreed upon in compromise, may be deducted from any sum then or later owing by the United States Government or a State agency to the person against whom the penalty or assessment has been assessed.

(d) Matters that were raised, or that could have been raised, in a hearing before an ALJ or in an appeal under section 1128A(e) of the Act may not be raised as a defense in a civil action by the United States to collect a penalty under this part.

§ 1003.1560 Notice to other agencies.

(a) Whenever a penalty, an assessment, or an exclusion becomes final, the following organizations and entities will be notified about such action and the reasons for it: The appropriate State or local medical or professional association; the appropriate quality improvement organization; as appropriate, the State agency that administers each State health care program; the appropriate Medicare carrier or intermediary; the appropriate State or local licensing agency or organization (including the Medicare and Medicaid State survey agencies); and the long-term-care ombudsman. In cases involving exclusions, notice will also be given to the public of the exclusion and its effective date.

(b) When the OIG proposes to exclude a nursing facility under this part, the OIG will, at the same time the facility is notified, notify the appropriate State licensing authority, the State Office of Aging, the long-term care ombudsman, and the State Medicaid agency of the OIG's intention to exclude the facility.

§ 1003.1570 Limitations.

No action under this part will be entertained unless commenced, in accordance with § 1003.1500(a), within 6 years from the date on which the violation occurred.

§ 1003.1580 Statistical sampling.

(a) In meeting the burden of proof in 42 CFR 1005.15, the OIG may introduce the results of a statistical sampling study as evidence of the number and amount of claims and/or requests for payment as described in this part that were presented, or caused to be presented, by the respondent. Such a statistical sampling study, if based upon an appropriate sampling and computed by valid statistical methods, shall constitute prima facie evidence of the number and amount of claims or requests for payment as described in this part.

(b) Once the OIG has made a prima facie case as described in paragraph (a) of this section, the burden of production shall shift to the respondent to produce evidence reasonably calculated to rebut the findings of the statistical sampling study. The OIG will then be given the opportunity to rebut this evidence.

§ 1003.1590 Effect of exclusion.

The effect of an exclusion will be as set forth in 42 CFR 1001.1901.

§ 1003.1600 Reinstatement.

A person who has been excluded in accordance with this part may apply for reinstatement at the end of the period of exclusion. The OIG will consider any request for reinstatement in accordance with the provisions of 42 CFR 1001.3001 through 1001.3004.

PART 1005 — [AMENDED]

■ 13. The authority citation for Part 1005 continues to read as follows:

Authority: 42 U.S.C. 405(a), 405(b), 1302, 1320a-7, 1320a-7a and 1320c-5.

■ 14. Section 1005.4 is amended by republishing the introductory text for paragraph (c) and revising paragraphs (c)(5) and (c)(6) to read as follows:

§ 1005.4 Authority of the ALJ.

* * * * *

(c) The ALJ does not have the authority to—

* * * * *

(5) Review the exercise of discretion by the OIG to exclude an individual or entity under section 1128(b) of the Act or under part 1003 of this chapter, or determine the scope or effect of the exclusion;

(6) Set a period of exclusion at zero, or reduce a period of exclusion to zero,

in any case where the ALJ finds that an individual or entity committed an act

described in section 1128(b) of the Act or under part 1003 of this chapter; or

* * * * *

Dated: January 16, 2014.

Daniel R. Levinson,
Inspector General.

Approved: January 28, 2014.

Kathleen Sebelius,
Secretary.

[FR Doc. 2014-10394 Filed 5-9-14; 8:45 am]

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